IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

AstraZeneca Access 360™

CODING, DOSAGE, and WASTAGE Guide for IMFINZI® (durvalumab)

This guide also includes information for IMFINZI + IMJUDO® (tremelimumab-actl) prescribed in combination.

Please see Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

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This guide serves as an all-indication resource providing information on coding, dosage, and wastage for IMFINZI and/or IMJUDO.*

*Support services for IMJUDO are available only when prescribed with IMFINZI for certain FDA-approved indications. IMJUDO is not approved as a monotherapy. Please refer to the full Prescribing Information when prescribing IMFINZI and IMJUDO.

dMMR=mismatch repair deficient; FDA=Food and Drug Administration.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information

There are no contraindications for IMFINZI® (durvalumab) or IMJUDO® (tremelimumab-actl).

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

General Coding Information

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

National Drug Code (NDC)

IMFINZI is supplied as single-use vials[1]

IMFINZI 10-digit NDC[1]

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

IMFINZI 11-digit NDC[1]

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

IMJUDO is supplied as single-use vials[2]

IMJUDO 10-digit NDC[2]

Dosage	Code
25 mg/1.25 mL single-dose vial	**0310-4505-25**
300 mg/15 mL single-dose vial	**0310-4535-30**

IMJUDO 11-digit NDC[2]

Dosage	Code
25 mg/1.25 mL single-dose vial	**00310-4505-25**
300 mg/15 mL single-dose vial	**00310-4535-30**

Current Procedural Terminology (CPT®)[3]

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists the **potential** CPT codes for your reference when submitting claims for IMFINZI and/or IMJUDO.

Code	Description
INFUSION ADMINISTRATION	
96XXX	Check payer's policy to obtain appropriate administration code
HOME INFUSION	
99XXX	Check payer's policy to obtain appropriate administration code

General Coding Information (cont'd)

Healthcare Common Procedure Coding System (HCPCS)[1,2,4]

Please contact the payer or Access 360 at **1-844-ASK-A360** (1-844-275-2360) for additional coding information.

IMFINZI HCPCS

Code	Description	Vial size	Billing units	NDC
J9173	Injection durvalumab, 10 mg	500 mg/10 mL	50 units	0310-4611-50
		120 mg/2.4 mL	12 units	0310-4500-12

IMJUDO HCPCS

Code	Description	Vial size	Billing units	NDC
J9347	Injection, tremelimumab-actl, 1 mg	25 mg/1.25 mL single-dose vial	25 units	00310-4505-25
		300 mg/15 mL single-dose vial	300 units	00310-4535-30

J-code effective dates for dates of service on or after July 1, 2023.

Modifiers[5]

Modifiers provide a means to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. The JW modifier below may be applicable in physician offices and hospital outpatient departments.

Modifier	Description	Indication and placement
JW	Drug amount discarded/ not administered to any patient	Unused drug remains after applicable dose is administered from a single-use vial • Centers for Medicare & Medicaid Services (CMS) has issued a discarded drug policy requiring use of the JW modifier, other payer requirements may vary • Typically, the modifier is appended to the drug HCPCS code on a line separate from that reporting the administered dose
JZ	Zero drug amount discarded/not administered to any patient	Modifier used to report no wastage from a single-use vial • CMS claims should include the JZ modifier when no wastage has occurred; other payer requirements may vary • Typically, the modifier is appended to the HCPCS code on the same line

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

General Coding Information (cont'd)

Place of Service Codes[6]

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.
21	Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.
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.

Revenue Codes for Hospital Outpatient Use[7]*

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 antiemetic drugs, immunosuppressive drugs, and others, must be billed with revenue codes 0634, 0635, or 0636 and detailed CPT or HCPCS coding according to UB-04 editor guidelines. Revenue code 0250—pharmacy is not appropriate for billing these categories of drugs.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; IV=intravenous.

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Sample Coding and Dosing

- Stage III Non-Small Cell Lung Cancer
- Metastatic Non-Small Cell Lung Cancer
- Resectable (Tumors ≥4 cm and/or Node Positive) Non-Small Cell Lung Cancer
- Extensive-Stage Small Cell Lung Cancer
- Limited-Stage Small Cell Lung Cancer
- Locally Advanced or Metastatic Biliary Tract Cancer
- Unresectable Hepatocellular Carcinoma
- Primary Advanced or Recurrent Endometrial Cancer (dMMR)
- Muscle Invasive Bladder Cancer
- Resectable Gastric or Gastroesophageal Junction Adenocarcinoma
- Bacillus Calmette-Guérin–Naive, High-Risk Non-Muscle-Invasive Bladder Cancer

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Stage III Non-Small Cell Lung Cancer

IMFINZI, as a single agent, is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).[1]

Dosage[1]

Recommended IMFINZI dosage for unresectable Stage III NSCLC*	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 10 mg/kg every 2 weeks **or** administer IMFINZI 1500 mg every 4 weeks	Until disease progression, unacceptable toxicity, or a maximum of 12 months
For patients with a body weight of <30 kg: Administer IMFINZI 10 mg/kg every 2 weeks	

*Following concurrent platinum-based chemotherapy and radiation therapy.[1]

ICD-10-CM Diagnosis Codes for the Stage III NSCLC Indication[8]

Code	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

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Evaluate clinical chemistries including liver enzymes, creatinine, adrenocorticotropic hormone (ACTH) level, and thyroid function at baseline and before each dose. 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. Withhold or permanently discontinue IMFINZI and IMJUDO depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI and IMJUDO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg 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.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Stage III Non-Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the Stage III NSCLC Indication[8] (cont'd)

Code	Description
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 left main bronchus
C34.32	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.80	Malignant neoplasm of upper lobe, right bronchus or lung
C34.81	Malignant neoplasm of upper lobe, left bronchus or 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
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 other malignant neoplasm of bronchus and lung (Conditions classifiable to C34)
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NSCLC=non-small cell lung cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Pneumonitis

IMFINZI and IMJUDO can cause immune-mediated pneumonitis, which may be fatal. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

- ***IMFINZI as a Single Agent***
  - In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2.4% (34/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions.
  - In patients who received recent prior radiation, the incidence of pneumonitis (including radiation pneumonitis) in patients with unresectable Stage III NSCLC following definitive chemoradiation within 42 days prior to initiation of IMFINZI in PACIFIC was 18.3% (87/475) in patients receiving IMFINZI and 12.8% (30/234) in patients receiving placebo. Of the patients who received IMFINZI (475), 1.1% were fatal and 2.7% were Grade 3 adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Metastatic Non-Small Cell Lung Cancer

IMFINZI, in combination with IMJUDO and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (mNSCLC) with no sensitizing epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations.[1,2]

Dosage[1]

Recommended IMFINZI + IMJUDO dosage for mNSCLC	Duration of therapy
For patients with a body weight of ≥30 kg: **Cycles 1-4 (Q3W):** • Platinum-based chemotherapy* • IMFINZI 1500 mg • IMJUDO 75 mg† **Cycles 5 and later (Q4W):** • Administer IMFINZI 1500 mg as a single agent until disease progression or intolerable toxicity and optional histology-based pemetrexed maintenance* • Administer IMJUDO 75 mg alongside IMFINZI only in Cycle 6 (Week 16)†	**Platinum-based chemotherapy:** Given Q3W for 4 cycles* **IMFINZI:** Until disease progression or intolerable toxicity **IMJUDO:** Up to a maximum of 5 doses†
For patients with a body weight of <30 kg: **Cycles 1-4 (Q3W):** • Platinum-based chemotherapy* • IMFINZI 20 mg/kg • IMJUDO 1 mg/kg† **Cycles 5 and later (Q4W):** • Administer IMFINZI 20 mg/kg as a single agent until disease progression or intolerable toxicity and optional histology-based pemetrexed maintenance* • Administer IMJUDO 1 mg/kg alongside IMFINZI only in Cycle 6 (Week 16)†	

*Options include pemetrexed + carboplatin/cisplatin (nonsquamous); gemcitabine + carboplatin/cisplatin (squamous); or nab-paclitaxel + carboplatin (either histology). Starting in Week 12, nonsquamous patients who received pemetrexed as part of the first-line regimen can continue pemetrexed maintenance Q4W until disease progression or intolerable toxicity.[1,2]

†If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of IMJUDO (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with IMFINZI Q4W.[1,2]

Q3W=every 3 weeks; Q4W=every 4 weeks.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Pneumonitis (cont'd)

- ***IMFINZI as a Single Agent*** (cont'd)
  - The incidence of pneumonitis (including radiation pneumonitis) in patients with LS-SCLC following chemoradiation within 42 days prior to initiation of IMFINZI in ADRIATIC was 14% (37/262) in patients receiving IMFINZI and 6% (16/265) in patients receiving placebo. Of the patients who received IMFINZI (262), 0.4% had a fatal adverse reaction and 2.7% had Grade 3 adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Metastatic Non-Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the Metastatic NSCLC Indication[8]

Code	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

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NSCLC=non-small cell lung cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Pneumonitis (cont'd)

- ***IMFINZI as a Single Agent*** (cont'd)
  - The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC or BTC when given in combination with chemotherapy.
- ***IMFINZI with IMJUDO***
  - Immune-mediated pneumonitis occurred in 1.3% (5/388) of patients receiving IMFINZI and IMJUDO, including fatal (0.3%) and Grade 3 (0.2%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Metastatic Non-Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the Metastatic NSCLC Indication[8] (cont'd)

Code	Description
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NSCLC=non-small cell lung cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Pneumonitis (cont'd)

- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated pneumonitis occurred in 3.5% (21/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including fatal (0.5%), and Grade 3 (1%) adverse reactions.

Immune-Mediated Colitis

IMFINZI with IMJUDO and platinum-based chemotherapy can cause immune-mediated colitis, which may be fatal. IMFINZI and IMJUDO can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) 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.

- ***IMFINZI as a Single Agent***
  - Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated colitis or diarrhea occurred in 6% (23/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (3.6%) adverse reactions. Intestinal perforation has been observed in other studies of IMFINZI and IMJUDO.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Resectable (Tumors ≥4 cm and/or Node Positive) Non-Small Cell Lung Cancer

IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (*ALK*) rearrangements.

Dosage[1]

Recommended IMFINZI dosage for neoadjuvant and adjuvant treatment of resectable NSCLC	Duration of therapy
For patients with a body weight of ≥30 kg: **Neoadjuvant:** Administer IMFINZI 1500 mg in combination with chemotherapy* every 3 weeks for up to 4 cycles prior to surgery **Adjuvant:** Administer IMFINZI 1500 mg as a single agent every 4 weeks for up to 12 cycles after surgery	Until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery
For patients with a body weight of <30 kg: **Neoadjuvant:** Administer IMFINZI 20 mg/kg every 3 weeks in combination with chemotherapy* for up to 4 cycles prior to surgery **Adjuvant:** Administer IMFINZI 20 mg/kg every 4 weeks for up to 12 cycles as a single agent after surgery	

*Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

ICD-10-CM Diagnosis Codes for the Resectable NSCLC Indication[8]

Code	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

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NSCLC=non-small cell lung cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Colitis (cont'd)

- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated colitis occurred in 6.5% (39/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy including fatal (0.2%) and Grade 3 (2.5%) adverse reactions. Intestinal perforation and large intestine perforation were reported in 0.1% of patients.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Resectable (Tumors ≥4 cm and/or Node Positive) Non-Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the Resectable NSCLC Indication[8] (cont'd)

Code	Description
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: lung cancer NOS
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z98.890	Other specified postprocedural states (personal history of surgery not elsewhere classified)

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NOS=not otherwise specified; NSCLC=non-small cell lung cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Hepatitis

IMFINZI and IMJUDO can cause immune-mediated hepatitis, which may be fatal.

- ***IMFINZI as a Single Agent***
  - Immune-mediated hepatitis occurred in 2.8% (52/1889) of patients receiving IMFINZI, including fatal (0.2%), Grade 4 (0.3%) and Grade 3 (1.4%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Extensive-Stage Small Cell Lung Cancer

IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).[1]

Dosage[1]

Recommended IMFINZI dosage for ES-SCLC	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 1500 mg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by IMFINZI 1500 mg every 4 weeks as a single agent	Until disease progression or unacceptable toxicity
For patients with a body weight of <30 kg: Administer IMFINZI 20 mg/kg in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by IMFINZI 10 mg/kg every 2 weeks as a single agent	

*Administer IMFINZI prior to chemotherapy (etoposide and either carboplatin or cisplatin) on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

ICD-10-CM Diagnosis Codes for the ES-SCLC Indication[8]

Code	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

ES-SCLC=extensive-stage small cell lung cancer; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Hepatitis (cont'd)

- ***IMFINZI with IMJUDO***
  - Immune-mediated hepatitis occurred in 7.5% (29/388) of patients receiving IMFINZI and IMJUDO, including fatal (0.8%), Grade 4 (0.3%) and Grade 3 (4.1%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Extensive-Stage Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the ES-SCLC Indication[8] (cont'd)

Code	Description
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
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

ES-SCLC=extensive-stage small cell lung cancer; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Hepatitis (cont'd)

- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated hepatitis occurred in 3.9% (23/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including fatal (0.3%), Grade 4 (0.5%), and Grade 3 (2%) adverse reactions.

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI and IMJUDO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Limited-Stage Small Cell Lung Cancer

IMFINZI, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).[1]

Dosage[1]

Recommended IMFINZI dosage for LS-SCLC*	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 1500 mg every 4 weeks	Until disease progression, unacceptable toxicity, or a maximum of 24 months
For patients with a body weight of <30 kg: Administer IMFINZI 20 mg/kg every 4 weeks	

*Following concurrent platinum-based chemotherapy and radiation therapy.[1]

ICD-10-CM Diagnosis Codes for the LS-SCLC Indication[8]

Code	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

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Adrenal Insufficiency***: (cont'd)
  - ***IMFINZI as a Single Agent***
    - Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Limited-Stage Small Cell Lung Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the LS-SCLC Indication[8] (cont'd)

Code	Description
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: lung cancer NOS
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation (personal history of exposure to therapeutic radiation)

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; LS-SCLC=limited-stage small cell lung cancer; NOS=not otherwise specified.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Adrenal Insufficiency***: (cont'd)
  - ***IMFINZI with IMJUDO***
    - Immune-mediated adrenal insufficiency occurred in 1.5% (6/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.3%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Locally Advanced or Metastatic Biliary Tract Cancer

IMFINZI, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).[1]

Dosage[1]

Recommended IMFINZI dosage for BTC	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 1500 mg in combination with chemotherapy* every 3 weeks (21 days) up to 8 cycles, followed by IMFINZI 1500 mg every 4 weeks as a single agent	Until disease progression or unacceptable toxicity
For patients with a body weight of <30 kg: Administer IMFINZI 20 mg/kg in combination with chemotherapy* every 3 weeks (21 days) up to 8 cycles, followed by IMFINZI 20 mg/kg every 4 weeks as a single agent	

*Administer IMFINZI prior to chemotherapy (gemcitabine and cisplatin) on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

ICD-10-CM Diagnosis Codes for the BTC Indication[8]

Code	Description
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Adrenal Insufficiency***: (cont'd)
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated adrenal insufficiency occurred in 2.2% (13/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.8%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Unresectable Hepatocellular Carcinoma

IMFINZI, in combination with IMJUDO, is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).[1,2]

Dosage[1,2]

Recommended IMFINZI + IMJUDO dosage for uHCC	Duration of therapy
For patients with a body weight of ≥30 kg: • Administer IMFINZI 1500 mg following a single dose of IMJUDO* 300 mg at Day 1 of Cycle 1 • Continue IMFINZI 1500 mg as a single agent every 4 weeks	After Cycle 1 of combination therapy, administer IMFINZI as a single agent every 4 weeks until disease progression or unacceptable toxicity
For patients with a body weight of <30 kg: • Administer IMFINZI 20 mg/kg following a single dose of IMJUDO* 4 mg/kg at Day 1 of Cycle 1 • Continue IMFINZI 20 mg/kg as a single agent every 4 weeks	

*Administer IMJUDO prior to IMFINZI on the same day. When IMJUDO is administered in combination with IMFINZI, refer to the Prescribing Information for IMJUDO dosing information.

ICD-10-CM Diagnosis Codes for the uHCC Indication[8]

Code	Description
C22.0	Liver cell carcinoma

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Hypophysitis***: IMFINZI and IMJUDO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated.
  - ***IMFINZI as a Single Agent***
    - Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
  - ***IMFINZI with IMJUDO***
    - Immune-mediated hypophysitis/hypopituitarism occurred in 1% (4/388) of patients receiving IMFINZI and IMJUDO.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated hypophysitis occurred in 1.3% (8/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.5%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Primary Advanced or Recurrent Endometrial Cancer (dMMR)

IMFINZI, in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) as determined by an FDA-approved test.[1]

Dosage[1]

Recommended IMFINZI dosage	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 1120 mg in combination with carboplatin and paclitaxel* every 3 weeks (21 days) for 6 cycles, followed by IMFINZI 1500 mg every 4 weeks as a single agent	Until disease progression or unacceptable toxicity
For patients with a body weight of <30 kg: Administer IMFINZI 15 mg/kg in combination with carboplatin and paclitaxel* every 3 weeks (21 days) for 6 cycles, followed by IMFINZI 20 mg/kg every 4 weeks as a single agent	

*Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for dosage information, as appropriate.

ICD-10-CM Diagnosis Codes for the Primary Advanced or Recurrent dMMR Endometrial Cancer Indication[8]

Code	Description
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C57.8	Malignant neoplasm of overlapping sites of female genital organs

FDA=Food and Drug Administration; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: IMFINZI and IMJUDO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Muscle Invasive Bladder Cancer

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).[1]

Dosage[1]

Recommended IMFINZI dosage	Duration of therapy
For patients with a body weight of ≥30 kg: **Neoadjuvant:** Administer IMFINZI 1500 mg in combination with gemcitabine and cisplatin* every 3 weeks for 4 cycles prior to surgery **Adjuvant:** Administer IMFINZI 1500 mg as a single agent every 4 weeks for up to 8 cycles after surgery	Until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity or a maximum of 8 cycles after surgery
For patients with a body weight of <30 kg: **Neoadjuvant:** Administer IMFINZI 20 mg/kg in combination with gemcitabine and cisplatin* every 3 weeks for 4 cycles prior to surgery **Adjuvant:** Administer IMFINZI 20 mg/kg as a single agent every 4 weeks for up to 8 cycles after surgery	

*Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

ICD-10-CM Diagnosis Codes for the MIBC Indication[8]

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

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: (cont'd)
  - ***IMFINZI as a Single Agent***
    - Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Muscle Invasive Bladder Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the MIBC Indication[8] (cont'd)

Code	Description
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
C68.0	Malignant neoplasm of urethra
Z90.6	Acquired absence of other parts of urinary tract
Z90.710	Acquired absence of both cervix and uterus
Z90.711	Acquired absence of uterus with remaining cervical stump
Z90.712	Acquired absence of cervix with remaining uterus
Z98.890	Other specified postprocedural states

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: (cont'd)
  - ***IMFINZI as a Single Agent*** (cont'd)
    - Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
    - Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Resectable Gastric or Gastroesophageal Junction Adenocarcinoma

IMFINZI in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).[1]

Dosage[1]

Recommended IMFINZI dosage for resectable GC/GEJC	Duration of therapy
For patients with a body weight of ≥30 kg: **Neoadjuvant:** IMFINZI 1500 mg IV every 4 weeks with FLOT*† for up to 2 cycles prior to surgery **Adjuvant:** IMFINZI 1500 mg IV every 4 weeks with FLOT*† for up to 2 cycles, followed by IMFINZI 1500 mg IV as a single agent every 4 weeks for up to 10 cycles	**Neoadjuvant:** Until disease progression that precludes definitive surgery or unacceptable toxicity **Adjuvant:** Until progression or recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery
For patients with a body weight of <30 kg: **Neoadjuvant:** IMFINZI 20 mg/kg IV every 4 weeks with FLOT*† for up to 2 cycles prior to surgery **Adjuvant:** IMFINZI 20 mg/kg IV every 4 weeks with FLOT*† for up to 2 cycles, followed by IMFINZI 20 mg/kg IV as a single agent every 4 weeks for up to 10 cycles	

*Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent(s) administered in combination with IMFINZI for recommended dosage information, as appropriate.

†FLOT chemotherapy is administered on days 1 and 15 of each 4-week cycle.

IV=intravenous.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: (cont'd)
  - ***IMFINZI with IMJUDO***
    - Immune-mediated thyroiditis occurred in 1.5% (6/388) of patients receiving IMFINZI and IMJUDO.
    - Immune-mediated hyperthyroidism occurred in 4.6% (18/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.3%) adverse reactions.
    - Immune-mediated hypothyroidism occurred in 11% (42/388) of patients receiving IMFINZI and IMJUDO.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Resectable Gastric or Gastroesophageal Junction Adenocarcinoma (cont'd)

ICD-10-CM Diagnosis Codes for the Resectable GC/GEJC Indication[8]

Code	Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: (cont'd)
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated thyroiditis occurred in 1.2% (7/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy.
    - Immune-mediated hyperthyroidism occurred in 5% (30/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.2%) adverse reactions.
    - Immune-mediated hypothyroidism occurred in 8.6% (51/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.5%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Resectable Gastric or Gastroesophageal Junction Adenocarcinoma (cont'd)

ICD-10-CM Diagnosis Codes for the Resectable GC/GEJC Indication[8] (cont'd)

Code	Description
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified

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

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Endocrinopathies (cont'd)

- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: (cont'd)
  - ***IMFINZI with Carboplatin and Paclitaxel***
    - Immune-mediated hypothyroidism occurred in 14% (34/235) of patients receiving IMFINZI in combination with carboplatin and paclitaxel.
- ***Type 1 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.
  - ***IMFINZI as a Single Agent***
    - Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.
  - ***IMFINZI with IMJUDO***
    - Two patients (0.5%, 2/388) had events of hyperglycemia requiring insulin therapy that had not resolved at last follow-up.
  - ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
    - Immune-mediated Type 1 diabetes mellitus occurred in 0.5% (3/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy including Grade 3 (0.3%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Bacillus Calmette-Guérin–Naive, High-Risk Non-Muscle-Invasive Bladder Cancer

IMFINZI in combination with Bacillus Calmette-Guérin (BCG) is indicated for the treatment of adult patients with BCG-naive, high-risk non-muscle-invasive bladder cancer (HR-NMIBC).[1]

Dosage[1]

Recommended IMFINZI IV dosage for BCG-naive high-risk NMIBC	Duration of therapy
For patients with a body weight of ≥30 kg: Administer IMFINZI 1500 mg IV every 4 weeks (28 days) for 13 cycles in combination with BCG* induction and maintenance	Until recurrence of high-risk disease, disease progression, unacceptable toxicity, or a maximum of 13 cycles
For patients with a body weight of <30 kg: Administer IMFINZI 20 mg/kg IV every 4 weeks (28 days) for 13 cycles in combination with BCG* induction and maintenance	

*Administer IMFINZI prior to BCG if given on the same day. Refer to the Prescribing Information for BCG dosing information.
IV=intravenous.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI and IMJUDO can cause immune-mediated nephritis.

- ***IMFINZI as a Single Agent***
  - Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Immune-mediated nephritis occurred in 1% (4/388) of patients receiving IMFINZI and IMJUDO, including Grade 3 (0.5%) adverse reactions.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated nephritis occurred in 0.7% (4/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.2%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Coding and Dosing (cont'd)

Bacillus Calmette-Guérin–Naive, High-Risk Non-Muscle-Invasive Bladder Cancer (cont'd)

ICD-10-CM Diagnosis Codes for the BCG-Naive High-Risk NMIBC Indication[8]

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

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NMIBC=non-muscle-invasive bladder cancer.

It is important to note that the codes identified in this resource 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 these codes does not guarantee reimbursement.

Important Safety Information (cont'd)

Immune-Mediated Dermatology Reactions

IMFINZI and IMJUDO can cause immune-mediated 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/L-1 and CTLA-4 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

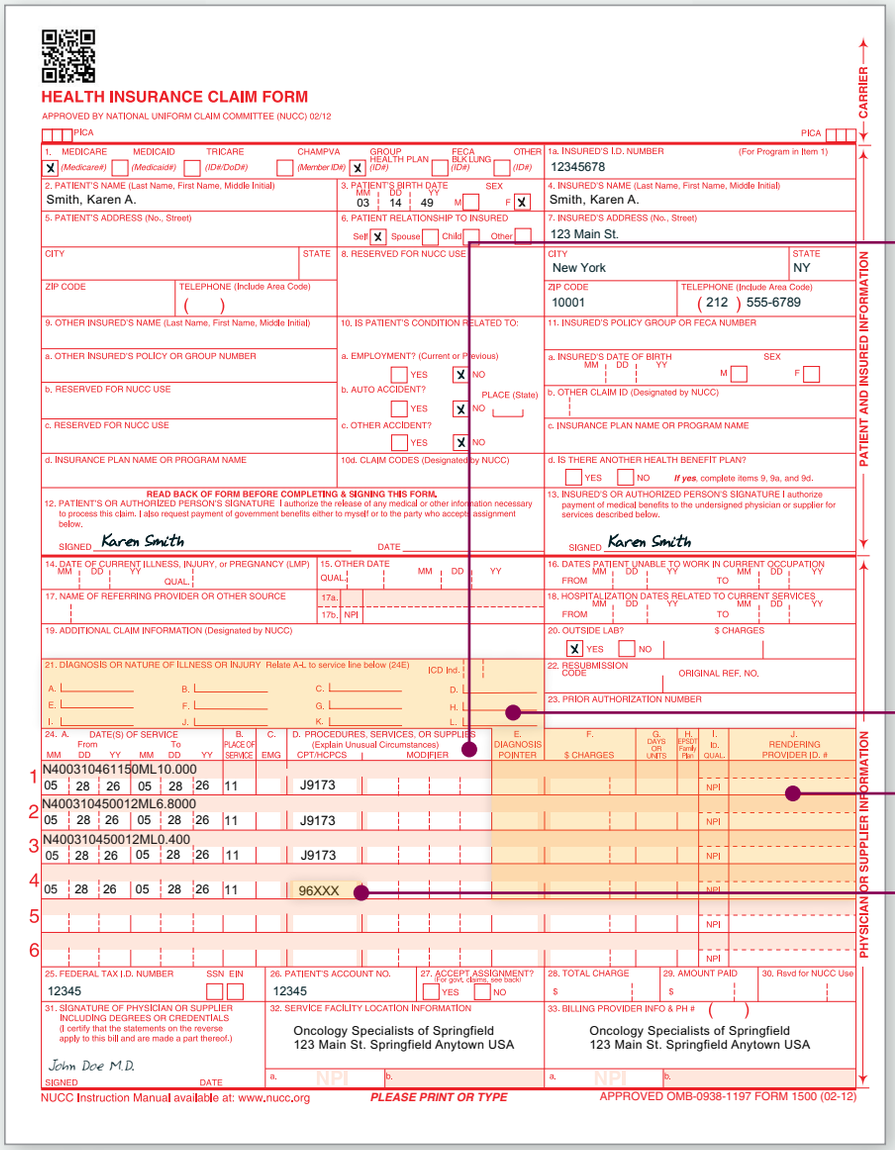
- ***IMFINZI as a Single Agent***
  - Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Sample Claim Forms

CMS-1500 Annotated Claim Form for IMFINZI

Prescribers use this form when billing insurers for medication administered in the physician's office and for their professional services.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE [X] (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN [X] (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 12345678

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

3. PATIENT'S BIRTH DATE: 03 14 49 SEX: M [ ] F [X]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

5. PATIENT'S ADDRESS (No., Street):

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 123 Main St.

CITY: | STATE: | 8. RESERVED FOR NUCC USE | CITY: New York | STATE: NY

ZIP CODE: | TELEPHONE (Include Area Code): ( ) | ZIP CODE: 10001 | TELEPHONE (Include Area Code): (212) 555-6789

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) | 10. IS PATIENT'S CONDITION RELATED TO: | 11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER | a. EMPLOYMENT? (Current or Previous) YES [ ] NO [X] | a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]

b. RESERVED FOR NUCC USE | b. AUTO ACCIDENT? YES [ ] NO [X] PLACE (State) | b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE | c. OTHER ACCIDENT? YES [ ] NO [X] | c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME | 10d. CLAIM CODES (Designated by NUCC) | d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES [ ] NO [ ] *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
SIGNED Karen Smith DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED Karen Smith

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. | 15. OTHER DATE QUAL. MM DD YY | 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE | 17a. | 17b. NPI | 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) | 20. OUTSIDE LAB? YES [X] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N400310461150ML10.000 05 28 26 05 28 26	11		J9173							NPI
2 N400310450012ML6.8000 05 28 26 05 28 26	11		J9173							NPI
3 N400310450012ML0.400 05 28 26 05 28 26	11		J9173							NPI
4 05 28 26 05 28 26	11		96XXX							NPI
5										NPI
6										NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN: 12345 | 26. PATIENT'S ACCOUNT NO.: 12345 | 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES [ ] NO [ ] | 28. TOTAL CHARGE $ | 29. AMOUNT PAID $ | 30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
John Doe M.D.
SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION
Oncology Specialists of Springfield
123 Main St. Springfield Anytown USA
a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )
Oncology Specialists of Springfield
123 Main St. Springfield Anytown USA
a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Medicare and many private payers require the use of modifier JW to report wastage of single-use vial drugs. Any discarded amount greater than a single billing unit should be reported on a separate line using the product's HCPCS code followed by the modifier JW. If no wastage is experienced, the modifier JZ should be entered after the HCPCS code on a single claim line for Medicare claims. Please refer to your payer's policy for more information.

Input applicable diagnosis code(s) here.

Complete sections E-J.

Check payer's policy to obtain appropriate administration code and input here.

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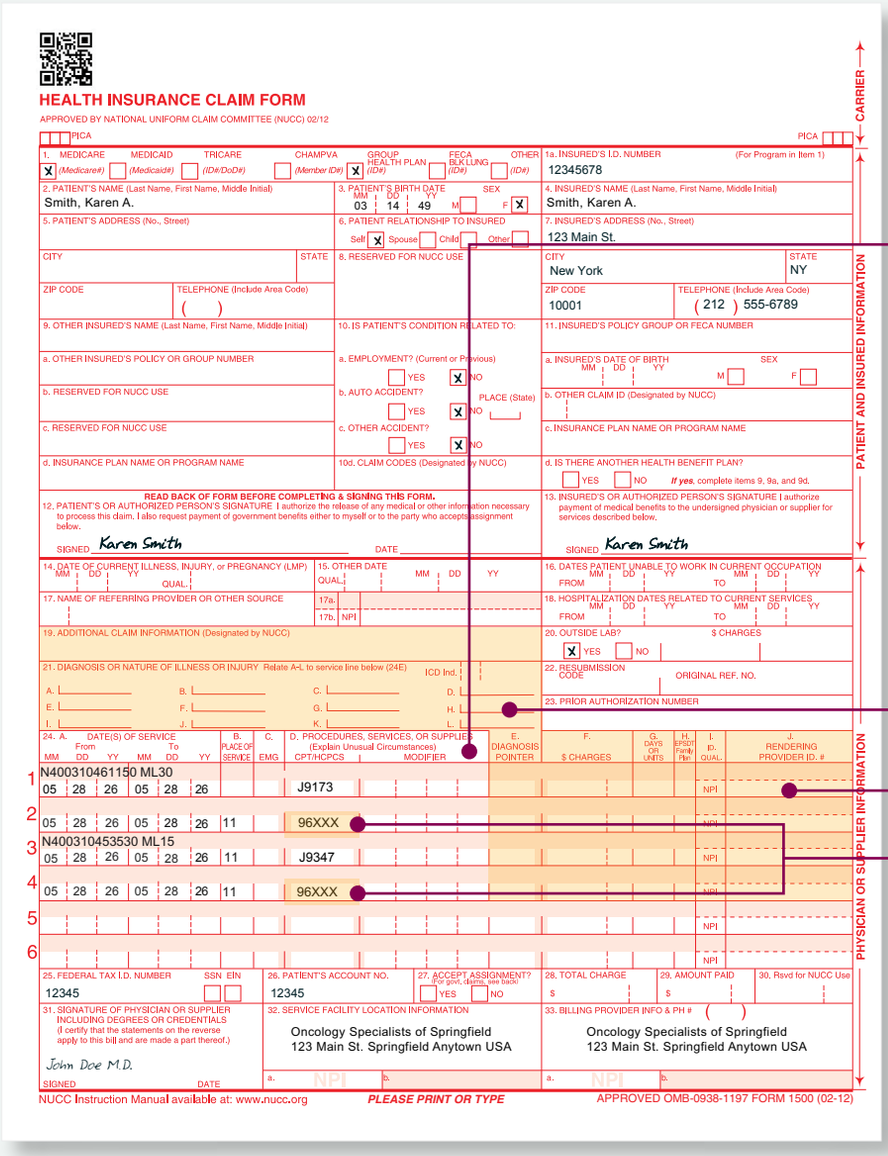
HCPCS=Healthcare Common Procedure Coding System.

Sample Claim Forms (cont'd)

CMS-1500 Annotated Claim Form for IMFINZI in Combination With IMJUDO

Prescribers use this form when billing insurers for medication administered in the physician's office and for their professional services.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE	MEDICAID	TRICARE	CHAMPVA	GROUP HEALTH PLAN	FECA BLK LUNG	OTHER
X (Medicare#)	(Medicaid#)	(ID#/DoD#)	(Member ID#)	X (ID#)	(ID#)	(ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 12345678

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

3. PATIENT'S BIRTH DATE: 03 14 49 — SEX: M F X

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Smith, Karen A.

5. PATIENT'S ADDRESS (No., Street):

6. PATIENT RELATIONSHIP TO INSURED: Self X Spouse Child Other

7. INSURED'S ADDRESS (No., Street): 123 Main St.

CITY: | STATE:

8. RESERVED FOR NUCC USE

CITY: New York | STATE: NY

ZIP CODE: | TELEPHONE (Include Area Code): ( )

ZIP CODE: 10001 | TELEPHONE (Include Area Code): (212) 555-6789

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous): YES X NO

a. INSURED'S DATE OF BIRTH MM DD YY — SEX: M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES X NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES X NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED Karen Smith DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED Karen Smith

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? X YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N400310461150 ML30 05 28 26	05 28 26			J9173						NPI	
2 05 28 26	05 28 26	11		96XXX						NPI	
3 N400310453530 ML15 05 28 26	05 28 26	11		J9347						NPI	
4 05 28 26	05 28 26	11		96XXX						NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN: 12345

26. PATIENT'S ACCOUNT NO.: 12345

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

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John Doe M.D.

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION: Oncology Specialists of Springfield, 123 Main St. Springfield Anytown USA

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( ): Oncology Specialists of Springfield, 123 Main St. Springfield Anytown USA

a. NPI b.

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PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

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Input applicable diagnosis code(s) here.

Complete sections E-J.

Check payer's policy to obtain appropriate administration code(s) and input here.

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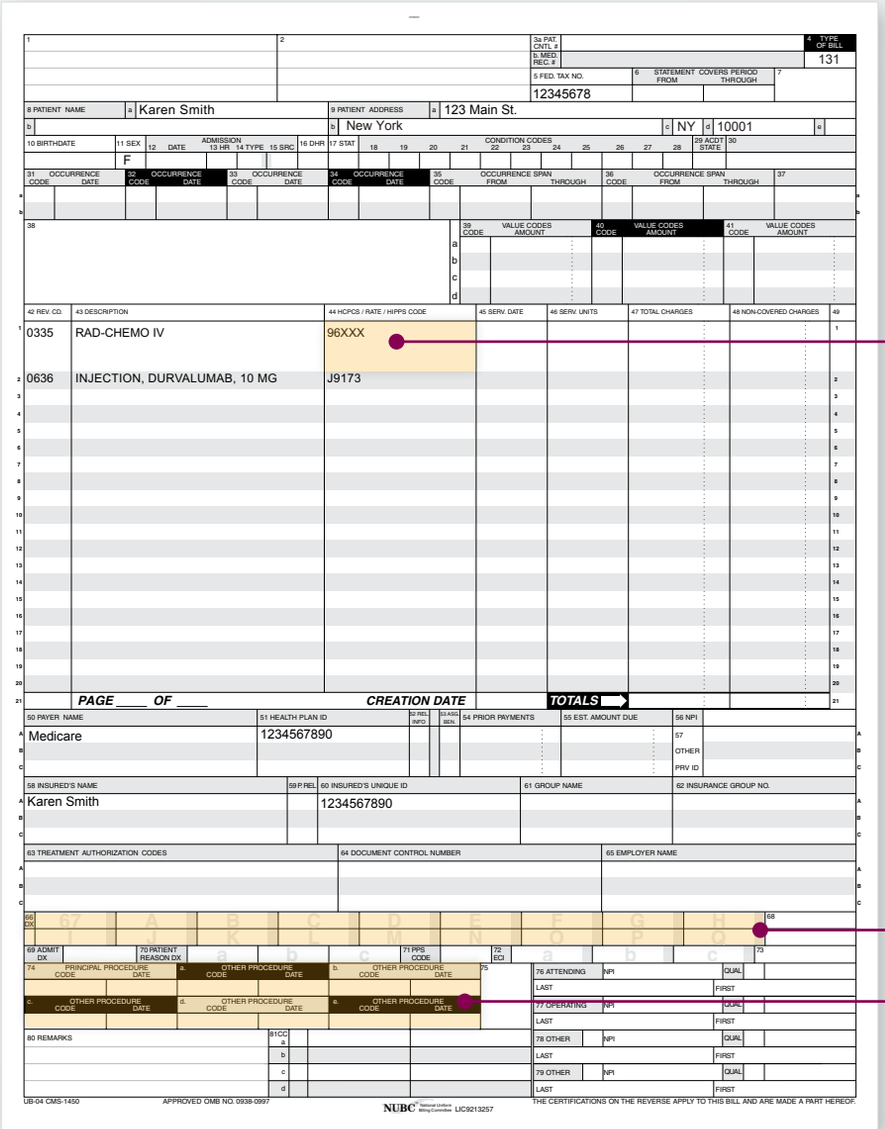
HCPCS=Healthcare Common Procedure Coding System.

Sample Claim Forms (cont'd)

UB-04 Annotated Claim Form for IMFINZI

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code and wastage modifier (JW or JZ). Please refer to payer-specific guidance.



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0335	RAD-CHEMO IV	96XXX				
0636	INJECTION, DURVALUMAB, 10 MG	J9173				

PAGE ____ OF ____ CREATION DATE TOTALS

50 PAYER NAME	51 HEALTH PLAN ID	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
Medicare	1234567890			

58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
Karen Smith		1234567890		

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Check payer's policy to obtain appropriate administration code and input here.

Input applicable diagnosis code(s) here.

Input Place of Service codes here.

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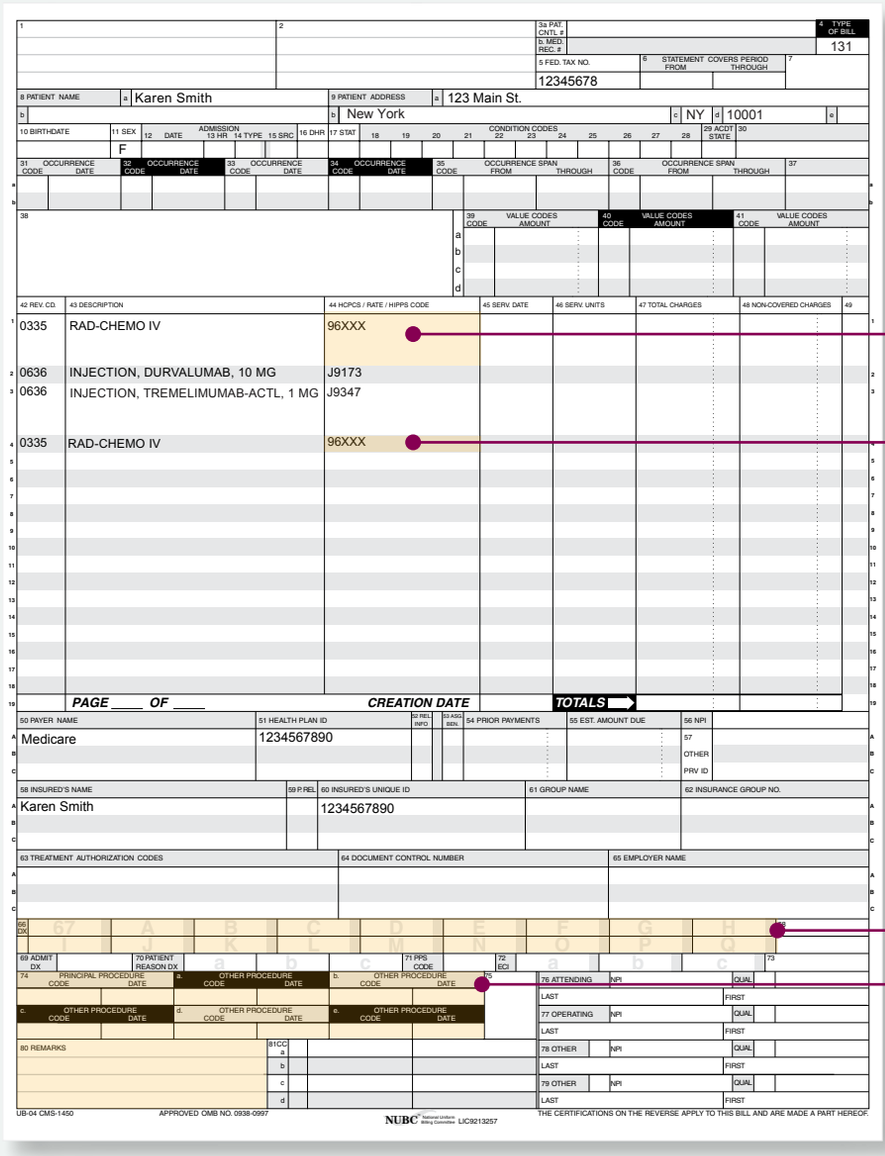
Sample Claim Forms (cont'd)

UB-04 Annotated Claim Form for IMFINZI in Combination With IMJUDO

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code and wastage modifier (JW or JZ). Please refer to payer-specific guidance.



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE
0335	RAD-CHEMO IV	96XXX
0636	INJECTION, DURVALUMAB, 10 MG	J9173
0636	INJECTION, TREMELIMUMAB-ACTL, 1 MG	J9347
0335	RAD-CHEMO IV	96XXX

8 PATIENT NAME: Karen Smith
9 PATIENT ADDRESS: 123 Main St.
New York, NY, 10001
4 TYPE OF BILL: 131
5 FED. TAX NO.: 12345678
10 BIRTHDATE: F
50 PAYER NAME: Medicare
51 HEALTH PLAN ID: 1234567890
58 INSURED'S NAME: Karen Smith
60 INSURED'S UNIQUE ID: 1234567890
UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC9213257 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

Check payer's policy to obtain appropriate administration code(s) and input here.

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Important Safety Information (cont'd)

Immune-Mediated Dermatology Reactions (cont'd)

- ***IMFINZI with IMJUDO***
  - Immune-mediated rash or dermatitis occurred in 4.9% (19/388) of patients receiving IMFINZI and IMJUDO, including Grade 4 (0.3%) and Grade 3 (1.5%) adverse reactions.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Immune-mediated rash or dermatitis occurred in 7.2% (43/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.3%) adverse reactions.

Immune-Mediated Pancreatitis

IMFINZI in combination with IMJUDO can cause immune-mediated pancreatitis. Immune-mediated pancreatitis occurred in 2.3% (9/388) of patients receiving IMFINZI and IMJUDO, including Grade 4 (0.3%) and Grade 3 (1.5%) adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI and IMJUDO or were reported with the use of other immune-checkpoint inhibitors.

- ***Cardiac/vascular***: Myocarditis, pericarditis, vasculitis.
- ***Nervous system***: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular***: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- ***Gastrointestinal***: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders***: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.
- ***Endocrine***: Hypoparathyroidism.
- ***Other (hematologic/immune)***: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

IMFINZI and IMJUDO can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI and IMJUDO based on the severity. See USPI Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses.

- ***IMFINZI as a Single Agent***
  - Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.
- ***IMFINZI with IMJUDO***
  - Infusion-related reactions occurred in 2.6% (10/388) of patients receiving IMFINZI and IMJUDO.
- ***IMFINZI with IMJUDO and Platinum-Based Chemotherapy***
  - Infusion-related reactions occurred in 2.9% (17/596) of patients receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody.

Important Safety Information (cont'd)

Complications of Allogeneic HSCT after IMFINZI (cont'd)

Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on their mechanism of action and data from animal studies, IMFINZI and IMJUDO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. In females of reproductive potential, verify pregnancy status prior to initiating IMFINZI and IMJUDO and advise them to use effective contraception during treatment with IMFINZI and IMJUDO and for 3 months after the last dose of IMFINZI and IMJUDO.

Lactation

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

Adverse Reactions

Unresectable Stage III NSCLC

- In patients with Stage III NSCLC in the PACIFIC study receiving IMFINZI (n=475), the most common adverse reactions (≥20%) 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 reactions (≥3%) were pneumonia (7%) and pneumonitis/radiation pneumonitis (3.4%).
- In patients with Stage III NSCLC in the PACIFIC study receiving 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%) 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.

Resectable NSCLC

- In patients with resectable NSCLC in the AEGEAN study, the most common adverse reactions (occurring in ≥20% of patients) were anemia, nausea, constipation, fatigue, musculoskeletal pain, and rash.
- In patients with resectable NSCLC in the neoadjuvant phase of the AEGEAN study receiving IMFINZI in combination with platinum-containing chemotherapy (n=401), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 6.7% of patients. Serious adverse reactions occurred in 21% of patients. The most frequent (≥1%) serious adverse reactions were pneumonia (2.7%), anemia (1.5%), myelosuppression (1.5%), vomiting (1.2%), neutropenia (1%), and acute kidney injury (1%). Fatal adverse reactions occurred in 2% of patients, including death due to COVID-19 pneumonia (0.5%), sepsis (0.5%), myocarditis (0.2%), decreased appetite (0.2%), hemoptysis (0.2%), and death not otherwise specified (0.2%). Of the 401 IMFINZI-treated patients who received neoadjuvant treatment and 398 placebo-treated patients who received neoadjuvant treatment, 1.7% (n=7) and 1% (n=4), respectively, did not receive surgery due to adverse reactions.
- In patients with resectable NSCLC in the adjuvant phase of the AEGEAN study receiving IMFINZI as a single agent (n=265), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 8% of patients. Serious adverse reactions occurred in 13% of patients. The most frequent serious adverse reactions reported in >1% of patients were pneumonia (1.9%), pneumonitis (1.1%), and COVID-19 (1.1%). Four fatal adverse reactions occurred during the adjuvant phase of the study, including COVID-19 pneumonia, pneumonia aspiration, interstitial lung disease and aortic aneurysm.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

Metastatic NSCLC

- In patients with mNSCLC in the POSEIDON study receiving IMFINZI and IMJUDO plus platinum-based chemotherapy (n=330), the most common adverse reactions (occurring in ≥20% of patients) were nausea (42%), fatigue (36%), musculoskeletal pain (29%), decreased appetite (28%), rash (27%), and diarrhea (22%).
- In patients with mNSCLC in the POSEIDON study receiving IMFINZI in combination with IMJUDO and platinum-based chemotherapy (n=330), permanent discontinuation of IMFINZI or IMJUDO due to an adverse reaction occurred in 17% of patients. Serious adverse reactions occurred in 44% of patients, with the most frequent serious adverse reactions reported in at least 2% of patients being pneumonia (11%), anemia (5%), diarrhea (2.4%), thrombocytopenia (2.4%), pyrexia (2.4%), and febrile neutropenia (2.1%). Fatal adverse reactions occurred in a total of 4.2% of patients.

Limited-stage Small Cell Lung Cancer

- In patients with limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), the most common adverse reactions occurring in ≥20% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (38%), and fatigue (21%). The most common Grade 3 or 4 adverse reactions (≥3%) were pneumonitis or radiation pneumonitis and pneumonia.
- In patients with limited-stage SCLC in the ADRIATIC study receiving IMFINZI (n=262), IMFINZI was permanently discontinued due to adverse reactions in 16% of the patients receiving IMFINZI. Serious adverse reactions occurred in 30% of patients receiving IMFINZI. The most frequent serious adverse reactions reported in ≥1% of patients receiving IMFINZI were pneumonitis or radiation pneumonitis (12%), and pneumonia (5%). Fatal adverse reactions occurred in 2.7% of patients who received IMFINZI including pneumonia (1.5%), cardiac failure, encephalopathy and pneumonitis (0.4% each).

Extensive-stage Small Cell Lung Cancer

- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), the most common adverse reactions (≥20%) were nausea (34%), fatigue/asthenia (32%), and alopecia (31%). The most common Grade 3 or 4 adverse reaction (≥3%) was fatigue/asthenia (3.4%).
- In patients with extensive-stage SCLC in the CASPIAN study receiving IMFINZI plus chemotherapy (n=265), IMFINZI was discontinued due to adverse reactions in 7% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 31% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 1% of patients were febrile neutropenia (4.5%), pneumonia (2.3%), anemia (1.9%), pancytopenia (1.5%), pneumonitis (1.1%), and COPD (1.1%). Fatal adverse reactions occurred in 4.9% of patients receiving IMFINZI plus chemotherapy.

Locally Advanced or Metastatic Biliary Tract Cancers (BTCs)

- In patients with locally advanced or metastatic BTCs in the TOPAZ-1 study receiving IMFINZI (n=338), the most common adverse reactions (occurring in ≥20% of patients) were fatigue (42%), nausea (40%), constipation (32%), decreased appetite (26%), abdominal pain (24%), rash (23%), and pyrexia (20%).
- In patients with locally advanced or metastatic BTCs in the TOPAZ-1 study receiving IMFINZI (n=338), discontinuation due to adverse reactions occurred in 6% of the patients receiving IMFINZI plus chemotherapy. Serious adverse reactions occurred in 47% of patients receiving IMFINZI plus chemotherapy. The most frequent serious adverse reactions reported in at least 2% of patients were cholangitis (7%), pyrexia (3.8%), anemia (3.6%), sepsis (3.3%) and acute kidney injury (2.4%). Fatal adverse reactions occurred in 3.6% of patients receiving IMFINZI plus chemotherapy. These include ischemic or hemorrhagic stroke (4 patients), sepsis (2 patients), and upper gastrointestinal hemorrhage (2 patients).

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

Unresectable Hepatocellular Carcinoma (HCC)

- In patients with unresectable HCC in the HIMALAYA study receiving IMFINZI and IMJUDO (n=388), the most common adverse reactions (occurring in ≥20% of patients) were rash (32%), diarrhea (27%), fatigue (26%), pruritus (23%), musculoskeletal pain (22%), and abdominal pain (20%).
- In patients with unresectable HCC in the HIMALAYA study receiving IMFINZI and IMJUDO (n=388), serious adverse reactions occurred in 41% of patients. Serious adverse reactions in >1% of patients included hemorrhage (6%), diarrhea (4%), sepsis (2.1%), pneumonia (2.1%), rash (1.5%), vomiting (1.3%), acute kidney injury (1.3%), and anemia (1.3%). Fatal adverse reactions occurred in 8% of patients who received IMFINZI and IMJUDO, including death (1%), hemorrhage intracranial (0.5%), cardiac arrest (0.5%), pneumonitis (0.5%), hepatic failure (0.5%), and immune-mediated hepatitis (0.5%). Permanent discontinuation of treatment regimen due to an adverse reaction occurred in 14% of patients.

Primary Advanced or Recurrent dMMR Endometrial Cancer

- In patients with primary advanced or recurrent dMMR endometrial cancer in the DUO-E study receiving IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent (n=44), the most common adverse reactions, including laboratory abnormalities (occurring in >20% of patients) were peripheral neuropathy (61%), musculoskeletal pain (59%), nausea (59%), alopecia (52%), fatigue (41%), abdominal pain (39%), constipation (39%), rash (39%), decreased magnesium (36%), increased ALT (32%), increased AST (30%), diarrhea (27%), vomiting (27%), cough (27%), decreased potassium (25%), dyspnea (25%), headache (23%), increased alkaline phosphatase (20%), and decreased appetite (18%). The most common Grade 3 or 4 adverse reactions (≥3%) were constipation (4.5%) and fatigue (4.5%).
- In patients with primary advanced or recurrent dMMR endometrial cancer in the DUO-E study receiving IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent (n=44), permanent discontinuation of IMFINZI due to adverse reactions occurred in 11% of patients. Serious adverse reactions occurred in 30% of patients who received IMFINZI with carboplatin and paclitaxel; the most common serious adverse reactions (≥4%) were constipation (4.5%) and rash (4.5%).

BCG-Naïve, High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

- In patients with BCG-naïve, high-risk NMIBC in the POTOMAC study receiving IMFINZI in combination with BCG, the most common (≥20%) adverse reactions, including laboratory abnormalities were increased glucose (43%), increased AST (43%), increased lipase (42%), increased ALT (42%), increased GGT (40%), urinary tract infection (40%), increased potassium (39%), dysuria (37%), decreased hemoglobin (35%), hematuria (33%), increased serum creatinine (30%), musculoskeletal pain (28%), decreased lymphocytes (27%), urinary frequency (26%), decreased sodium (23%), fatigue (21%), rash (20%), and pyrexia (20%).
- In patients with BCG-naïve, high-risk NMIBC in the POTOMAC study receiving IMFINZI in combination with BCG, permanent discontinuation of IMFINZI due to adverse reactions occurred in 18% of patients. The adverse reactions which resulted in permanent discontinuation of IMFINZI (≥1%) were hepatitis (1.8%), acute kidney injury (1.2%), and diarrhea (1.2%). Serious adverse reactions occurred in 32% of patients. The most common (≥1%) serious adverse reactions were urinary tract infection (4.5%), COVID (1.8%), hepatitis (1.5%), dysuria (1.2%), and prostate cancer (1.2%). Fatal adverse reactions occurred in 2.4% of patients who received IMFINZI in combination with BCG, including congestive cardiac failure (0.6%), COVID (0.3%), cardiovascular disorder (0.3%), dementia with Lewy bodies (0.3%), and pancreatic cancer (0.3%).

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

Muscle-Invasive Bladder Cancer (MIBC)

- In patients with MIBC, the most common adverse reactions, including laboratory abnormalities, in the overall study (occurring in ≥20% of patients) were decreased hemoglobin, decreased neutrophils, increased blood creatinine, decreased sodium, nausea, increased ALT, decreased calcium, decreased platelets, fatigue, increased potassium, decreased lymphocytes, increased AST, constipation, decreased magnesium, decreased appetite, increased alkaline phosphatase, rash, pyrexia, diarrhea, vomiting and abdominal pain.
- In patients with MIBC in the neoadjuvant phase of the NIAGARA study receiving IMFINZI in combination with gemcitabine and cisplatin (n=530), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 9% of patients. Serious adverse reactions occurred in 24% of patients; the most frequent (≥1%) serious adverse reactions were pulmonary embolism (1.9%), febrile neutropenia (1.5%), acute kidney injury (1.3%), thrombocytopenia (1.3%), urinary tract infection (1.3%), and pneumonia (1.3%). Fatal adverse reactions occurred in 1.1% of patients including sepsis, myocardial infarction, and pulmonary embolism (0.2% each). One fatal adverse reaction of pneumonia was reported in 1 (0.2%) patient in the post-surgery phase before adjuvant treatment started. Of the 530 patients in the IMFINZI treatment arm and 526 patients in the chemotherapy treatment arm who received neoadjuvant treatment, 1 (0.2%) patient in each treatment arm did not receive surgery due to adverse reactions. The adverse reaction that led to cancellation of surgery in the IMFINZI treatment arm was interstitial lung disease.
- In patients with MIBC in the adjuvant phase of the NIAGARA study receiving IMFINZI as a single agent (n=383), permanent discontinuation of adjuvant IMFINZI due to an adverse reaction occurred in 5% of patients. Serious adverse reactions occurred in 26% of patients. The most frequent serious adverse reactions (occurring in ≥1% of patients) were urinary tract infection (7%), acute kidney injury (3.7%), hydronephrosis (2.1%), pyelonephritis (2.1%), urosepsis (1.8%) and sepsis (1.6%). Fatal adverse reactions occurred in 1.8% of patients, including COVID-19, severe acute respiratory syndrome, cardiopulmonary failure, gastrointestinal hemorrhage, and chronic hepatic failure (0.3% each).

Resectable Gastric Cancer/Gastroesophageal Junction Adenocarcinoma (GC/GEJC)

- In patients with resectable GC/GEJC, the most common adverse reactions in the overall study (occurring in ≥20% of patients) were diarrhea, nausea, peripheral neuropathy, fatigue, alopecia, decreased appetite, rash, abdominal pain, vomiting, musculoskeletal pain, pyrexia, and stomatitis.
- In patients with resectable GC/GEJC in the neoadjuvant phase of the MATTERHORN study receiving IMFINZI in combination with FLOT chemotherapy (n=475), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 2.5% of patients. Serious adverse reactions occurred in 21% of patients; the most frequent (≥2%) serious adverse reaction was diarrhea (2.5%). Deaths occurred in 1.9% of patients; deaths of ≥2 patients included septic shock (0.6%) and acute coronary syndrome (0.4%). Of the 475 patients in the IMFINZI + FLOT chemotherapy treatment arm and 469 patients in the placebo + FLOT chemotherapy treatment arm who received neoadjuvant treatment, 0.6% and 0.4% of patients, respectively, did not receive surgery due to adverse reactions, and 2.3% and 2.6% of patients, respectively, had a delay in surgery due to ARs.
- In patients with resectable GC/GEJC in the adjuvant phase of the MATTERHORN study receiving IMFINZI in combination with FLOT chemotherapy (n=365), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 7% of patients. Serious adverse reactions occurred in 29% of patients; the most frequent (≥2%) serious adverse reaction was pneumonia (2.5%). Deaths occurred in 2.2% of patients; deaths of ≥2 patients included gastrointestinal perforation (0.5%) and COVID-19 (0.5%).

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

Resectable Gastric Cancer/Gastroesophageal Junction Adenocarcinoma (GC/GEJC) (cont'd)

- In patients with resectable GC/GEJC in the adjuvant phase of the MATTERHORN study receiving IMFINZI alone (n=345), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 6% of patients. Serious adverse reactions occurred in 14% of patients. Deaths occurred in 1.7% of patients; deaths of ≥2 patients included gastrointestinal perforation (0.6%) and COVID-19 (0.6%).

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

Indications:

IMFINZI, as a single agent, is indicated for the treatment of adult patients with unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).

IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

IMFINZI, in combination with IMJUDO and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.

IMFINZI, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT).

IMFINZI, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMFINZI, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

IMFINZI in combination with IMJUDO is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

IMFINZI in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) as determined by an FDA-authorized test.

IMFINZI in combination with Bacillus Calmette-Guérin (BCG) is indicated for the treatment of adult patients with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC).

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC).

IMFINZI in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

You may report side effects related to AstraZeneca products.

The AstraZeneca Access 360™ program provides personal support to help streamline access and reimbursement for IMFINZI and/or IMJUDO*

For more information, please contact AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM - 6 PM ET.

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

www.MyAccess360.com

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

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*Support services for IMJUDO are available only when prescribed with IMFINZI for certain FDA-approved indications. IMJUDO is not approved as a monotherapy. Please refer to the full Prescribing Information when prescribing IMFINZI and IMJUDO.

FDA=US Food and Drug Administration.

References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026. **2.** IMJUDO® (tremelimumab-actl) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **3.** CPT codes, descriptions and other data only are copyright 2023 American Medical Association. All rights reserved. **4.** EncoderPro for Payers Professional; Copyright © 2023 Thomson MICROMEDEX. All rights reserved. **5.** Centers for Medicare & Medicaid Services. Medicare program discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Accessed May 28, 2026. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **6.** Centers for Medicare & Medicaid Services. Place of service code set. Updated May 2, 2024. Accessed May 28, 2026. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set **7.** Noridian Healthcare Solutions. Revenue codes. Updated February 12, 2026. Accessed May 28, 2026. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **8.** Centers for Medicare & Medicaid Services. ICD-10. Updated March 10, 2026. Accessed May 28, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes