IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL | IMJUDO® tremelimumab-actl Injection for Intravenous Use 20 mg/mL | AstraZeneca Access 360™

Digital Access and Reimbursement Guide for IMFINZI® (durvalumab)

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

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Welcome to the AstraZeneca Access 360™ Program!

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

- ☑ Assistance with understanding patient insurance coverage and pharmacy options
- ☑ Prior authorization support
- ☑ Claims and appeal process support
- ☑ Eligibility requirements and enrollment assistance with AstraZeneca's Co-pay Savings Programs
- ☑ Referrals to the AZ&Me™ Prescription Savings Program, AstraZeneca's patient assistance program
- ☑ Information about independent charitable patient assistance foundations

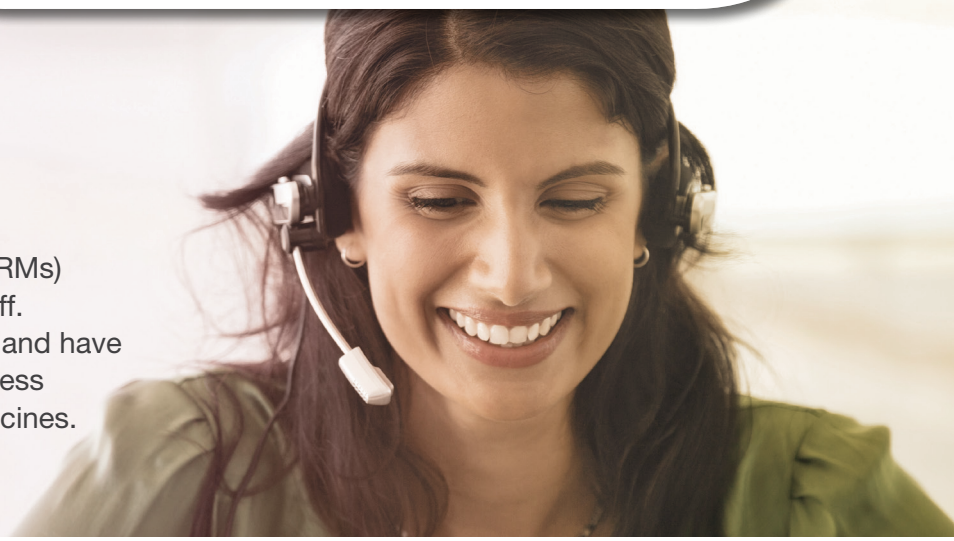
To learn more about the Access 360 program, please call **1-844-ASK-A360** (1-844-275-2360) Monday through Friday, 8 AM - 6 PM ET or visit **www.MyAccess360.com**.

This guide contains information to help you and your office staff understand the access and reimbursement process and provides links to additional Access 360 resources.

This description of the Access 360 program is for informational purposes only. Access 360 does not file claims or appeals on behalf of healthcare professionals or patients and makes no representation or guarantee concerning reimbursement or coverage for any service or item.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Your Field Reimbursement Manager



AstraZeneca Field Reimbursement Managers (FRMs) are a resource for patients, HCPs, and office staff. FRMs provide regional, patient-specific support and have extensive expertise that can help streamline access and reimbursement for select AstraZeneca medicines.

Your FRM can provide:

- Access and reimbursement support for providers and office staff, onsite or via telephone*
- Personalized support to help connect patients to affordability programs
- Resources to educate providers and office staff about support services offered by AstraZeneca Access 360™
- Timely responses to questions about access and reimbursement
- Access to innovative technology resources such as the Access 360 Provider Portal

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)

Access360@AstraZeneca.com

One MedImmune Way, Gaithersburg, MD 20878

*Please note that FRMs are not able to file claims on behalf of providers or office staff.
HCP=healthcare provider.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Contents of This Guide and Overview of Key Steps*

HCP | Access 360 | Patient

*Please note that patient and/or HCP attestation/consent may be required. The resources in this guide may be used 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.

‡If PA is denied, Access 360 can assist with appeals support.
FDA=US Food and Drug Administration; HCP=healthcare provider; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

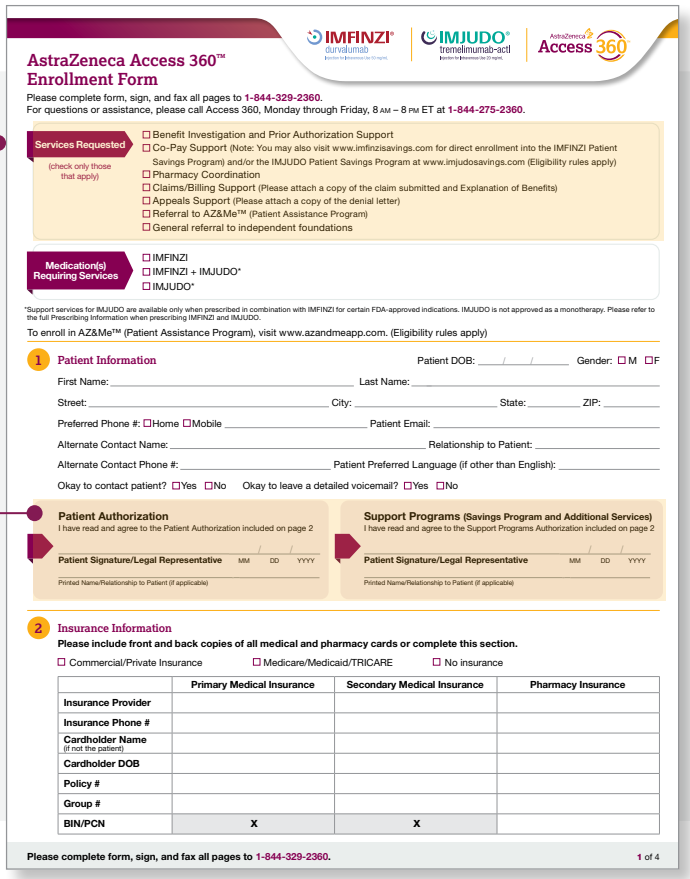
Enrollment Form

The Enrollment Form is used to capture necessary patient, provider, and prescription information to start a new request for support from Access 360. We recommend that you and your patient fill out this form so your patient can enroll in Access 360. The patient and the provider are each responsible for completing their designated sections of this form. Please note this form can be used to enroll patients who are prescribed IMFINZI and/or IMJUDO.*

Download the Enrollment Form from MyAccess360.com.

SERVICES REQUESTED
This section allows the office to specify which services Access 360 completes.

PATIENT SIGNATURE
This section is for the patient to complete in the office. The first signature will facilitate the level of support Access 360 can provide. The second signature allows Access 360 to enroll the patient into the Co-pay Savings Program (eligibility rules apply) and send the patient treatment information.



AstraZeneca Access 360™
Enrollment Form

Please complete form, sign, and fax all pages to 1-844-329-2360.
For questions or assistance, please call Access 360, Monday through Friday, 8 AM – 8 PM ET at 1-844-275-2360.

Services Requested (check only those that apply)
- ☐ Benefit Investigation and Prior Authorization Support
- ☐ Co-Pay Support (Note: You may also visit www.imfinzisavings.com for direct enrollment into the IMFINZI Patient Savings Program) and/or the IMJUDO Patient Savings Program at www.imjudosavings.com (Eligibility rules apply)
- ☐ Pharmacy Coordination
- ☐ Claims/Billing Support (Please attach a copy of the claim submitted and Explanation of Benefits)
- ☐ Appeals Support (Please attach a copy of the denial letter)
- ☐ Referral to AZ&Me™ (Patient Assistance Program)
- ☐ General referral to independent foundations

Medication(s) Requiring Services
- ☐ IMFINZI
- ☐ IMFINZI + IMJUDO*
- ☐ IMJUDO*

*Support services for IMJUDO are available only when prescribed in combination 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.

To enroll in AZ&Me™ (Patient Assistance Program), visit www.azandmeapp.com. (Eligibility rules apply)

1 Patient Information
Patient DOB: ___/___/___ Gender: ☐M ☐F
First Name: _____ Last Name: _____
Street: _____ City: _____ State: _____ ZIP: _____
Preferred Phone #: ☐Home ☐Mobile _____ Patient Email: _____
Alternate Contact Name: _____ Relationship to Patient: _____
Alternate Contact Phone #: _____ Patient Preferred Language (if other than English): _____
Okay to contact patient? ☐Yes ☐No Okay to leave a detailed voicemail? ☐Yes ☐No

Patient Authorization
I have read and agree to the Patient Authorization included on page 2
Patient Signature/Legal Representative MM DD YYYY
Printed Name/Relationship to Patient (if applicable)

Support Programs (Savings Program and Additional Services)
I have read and agree to the Support Programs Authorization included on page 2
Patient Signature/Legal Representative MM DD YYYY
Printed Name/Relationship to Patient (if applicable)

2 Insurance Information
Please include front and back copies of all medical and pharmacy cards or complete this section.
☐ Commercial/Private Insurance ☐ Medicare/Medicaid/TRICARE ☐ No insurance

	Primary Medical Insurance	Secondary Medical Insurance	Pharmacy Insurance
Insurance Provider			
Insurance Phone #			
Cardholder Name (if not the patient)			
Cardholder DOB			
Policy #			
Group #			
BIN/PCN	X	X	

Please complete form, sign, and fax all pages to 1-844-329-2360. 1 of 4

All sections of the enrollment form, with the exception of the patient authorization, can be completed by an authorized HCP who can either:

- Download and print the enrollment form here. Once signed, fax the document to Access 360. This form will also need to be signed by the patient.
- Complete the form electronically through the HCP portal here.

If patient or legally authorized representative is unable to sign the enrollment form, they can instead:

- Submit signature electronically at www.MyAccess360.com.
- Download and print the patient authorization form here. Once signed, fax the document to Access 360.
- Call Access 360 to provide verbal authorization (1-844-275-2360).

*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; HCP=healthcare provider.

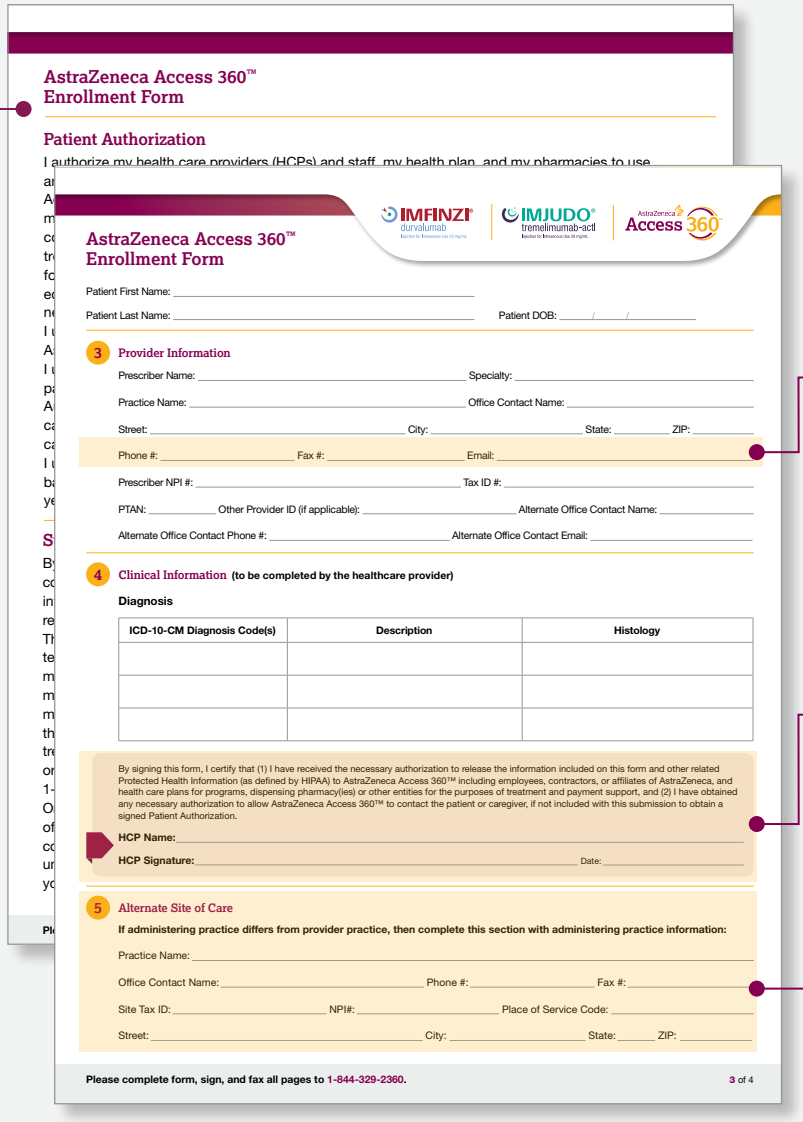
Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Enrollment Form (cont'd)

Please note this form can be used to enroll patients who are prescribed IMFINZI and/or IMJUDO.*

Download the Enrollment Form from MyAccess360.com.

PATIENT AUTHORIZATION AND SUPPORT PROGRAMS (PAGE 2)
This page details the authorization of the patient to release specific personal information to Access 360 and explains available support options for covering the cost of their medication, if necessary.



AstraZeneca Access 360™
Enrollment Form

Patient Authorization

IMFINZI® durvalumab | IMJUDO® tremelimumab-actl | AstraZeneca Access 360™

AstraZeneca Access 360™
Enrollment Form

Patient First Name: _____

Patient Last Name: _____ Patient DOB: ___/___/_____

3 Provider Information

Prescriber Name: _____ Specialty: _____

Practice Name: _____ Office Contact Name: _____

Street: _____ City: _____ State: _____ ZIP: _____

Phone #: _____ Fax #: _____ Email: _____

Prescriber NPI #: _____ Tax ID #: _____

PTAN: _____ Other Provider ID (if applicable): _____ Alternate Office Contact Name: _____

Alternate Office Contact Phone #: _____ Alternate Office Contact Email: _____

4 Clinical Information (to be completed by the healthcare provider)

Diagnosis

ICD-10-CM Diagnosis Code(s)	Description	Histology

By signing this form, I certify that (1) I have received the necessary authorization to release the information included on this form and other related Protected Health Information (as defined by HIPAA) to AstraZeneca Access 360™ including employees, contractors, or affiliates of AstraZeneca, and health care plans for programs, dispensing pharmacy(ies) or other entities for the purposes of treatment and payment support, and (2) I have obtained any necessary authorization to allow AstraZeneca Access 360™ to contact the patient or caregiver, if not included with this submission to obtain a signed Patient Authorization.

HCP Name: _____

HCP Signature: _____ Date: _____

5 Alternate Site of Care

If administering practice differs from provider practice, then complete this section with administering practice information:

Practice Name: _____

Office Contact Name: _____ Phone #: _____ Fax #: _____

Site Tax ID: _____ NPI#: _____ Place of Service Code: _____

Street: _____ City: _____ State: _____ ZIP: _____

Please complete form, sign, and fax all pages to 1-844-329-2360. 3 of 4

PROVIDER INFORMATION
The phone number, fax number, and email can refer directly to the office contact's information. Providing this information may help facilitate communications with Access 360.

HCP SIGNATURE
This signature allows Access 360 to complete initial research for the requested services. The signature can be provided by the prescribing physician, office staff, or practice manager.

ALTERNATE SITE OF CARE
This section is required for infused products if the prescribing facility is different from the treating facility.

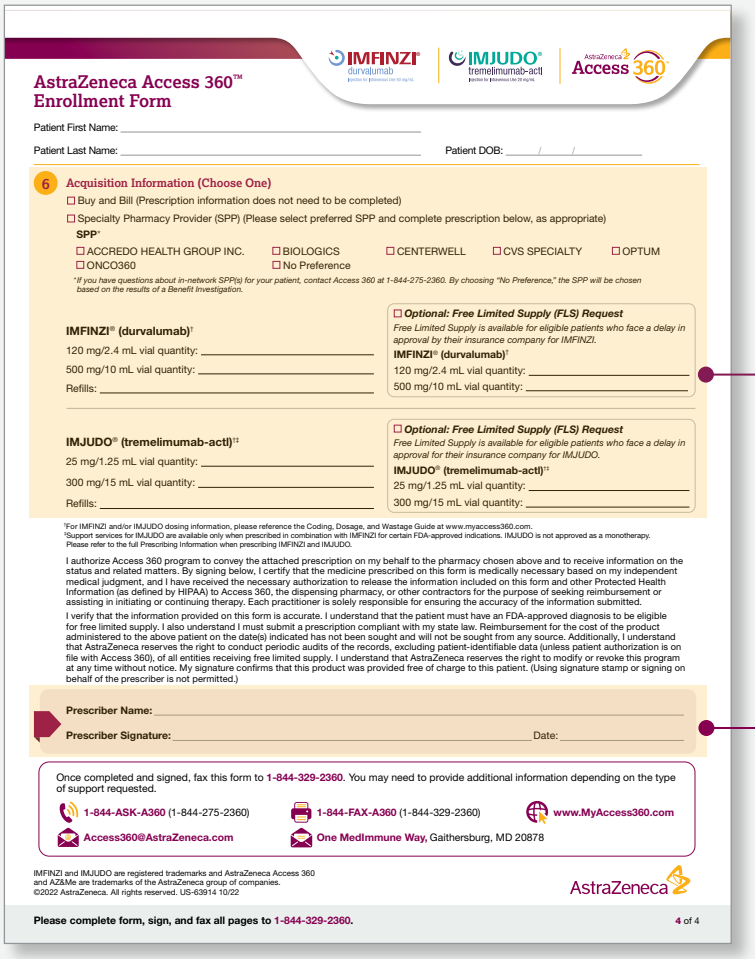
*Support services for IMJUDO are available only when prescribed with IMFINZI for certain FDA-approved indications. IMJUDO is not approved as a monotherapy. Please refer to the full Prescribing Information when prescribing IMFINZI and IMJUDO.
FDA=US Food and Drug Administration; HCP=healthcare provider.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Enrollment Form (cont'd)

Please note this form can be used to enroll patients who are prescribed IMFINZI and/or IMJUDO.*

Download the Enrollment Form from MyAccess360.com.



AstraZeneca Access 360™ Enrollment Form

Patient First Name: _____

Patient Last Name: _____ Patient DOB: ____/____/____

6 Acquisition Information (Choose One)

☐ Buy and Bill (Prescription information does not need to be completed)

☐ Specialty Pharmacy Provider (SPP) (Please select preferred SPP and complete prescription below, as appropriate)

SPP*

☐ ACCREDO HEALTH GROUP INC. ☐ BIOLOGICS ☐ CENTERWELL ☐ CVS SPECIALTY ☐ OPTUM
☐ ONCO360 ☐ No Preference

*If you have questions about in-network SPP(s) for your patient, contact Access 360 at 1-844-275-2360. By choosing "No Preference," the SPP will be chosen based on the results of a Benefit Investigation.

IMFINZI® (durvalumab)†
120 mg/2.4 mL vial quantity: _____
500 mg/10 mL vial quantity: _____
Refills: _____

☐ ***Optional: Free Limited Supply (FLS) Request***
Free Limited Supply is available for eligible patients who face a delay in approval by their insurance company for IMFINZI.
IMFINZI® (durvalumab)†
120 mg/2.4 mL vial quantity: _____
500 mg/10 mL vial quantity: _____

IMJUDO® (tremelimumab-actl)†‡
25 mg/1.25 mL vial quantity: _____
300 mg/15 mL vial quantity: _____
Refills: _____

☐ ***Optional: Free Limited Supply (FLS) Request***
Free Limited Supply is available for eligible patients who face a delay in approval for their insurance company for IMJUDO.
IMJUDO® (tremelimumab-actl)†‡
25 mg/1.25 mL vial quantity: _____
300 mg/15 mL vial quantity: _____

†For IMFINZI and/or IMJUDO dosing information, please reference the Coding, Dosage, and Wastage Guide at www.myaccess360.com.
‡Support services for IMJUDO are available only when prescribed in combination 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.

I authorize Access 360 program to convey the attached prescription on my behalf to the pharmacy chosen above and to receive information on the status and related matters. By signing below, I certify that the medicine prescribed on this form is medically necessary based on my independent medical judgment, and I have received the necessary authorization to release the information included on this form and other Protected Health Information (as defined by HIPAA) to Access 360, the dispensing pharmacy, or other contractors for the purpose of seeking reimbursement or assisting in initiating or continuing therapy. Each practitioner is solely responsible for ensuring the accuracy of the information submitted.

I verify that the information provided on this form is accurate. I understand that the patient must have an FDA-approved diagnosis to be eligible for free limited supply. I also understand I must submit a prescription compliant with my state law. Reimbursement for the cost of the product administered to the above patient on the date(s) indicated has not been sought and will not be sought from any source. Additionally, I understand that AstraZeneca reserves the right to conduct periodic audits of the records, excluding patient-identifiable data (unless patient authorization is on file with Access 360), of all entities receiving free limited supply. I understand that AstraZeneca reserves the right to modify or revoke this program at any time without notice. My signature confirms that this product was provided free of charge to this patient. (Using signature stamp or signing on behalf of the prescriber is not permitted.)

Prescriber Name: _____
Prescriber Signature: _____ Date: _____

Once completed and signed, fax this form to **1-844-329-2360**. You may need to provide additional information depending on the type of support requested.

1-844-ASK-A360 (1-844-275-2360) | **1-844-FAX-A360** (1-844-329-2360) | **www.MyAccess360.com**
Access360@AstraZeneca.com | **One MedImmune Way**, Gaithersburg, MD 20878

AstraZeneca

Please complete form, sign, and fax all pages to 1-844-329-2360. 4 of 4

PRESCRIPTION INFORMATION

This section requires you to provide detailed information about the prescription, such as product dose.

This section may also include information regarding the **Free Limited Supply (FLS) Request**, which applies to select AstraZeneca medications. If applicable, completing this section may allow a limited supply of free medication for patients (eligibility rules apply).

PRESCRIBER SIGNATURE

This section must be signed by the prescriber if this form is being used to fill a prescription. For faxing purposes, this page can be detached from the form.

*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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide

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.

Download the Coding, Dosage, and Wastage Guide from MyAccess360.com.

General Coding Information

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

Coding, Dosage, and Wastage Guide (cont'd)

Modifiers[4]

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 modifiers 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 and 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 Healthcare Common Procedure Coding System (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

Healthcare Common Procedure Coding System (HCPCS)[1,2,5]

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

The J Code is in effect for dates of service on or after July 1, 2023.

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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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.

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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (cont'd)

Sample Coding Information

Unresectable Stage III Non-Small Cell Lung Cancer

IMFINZI 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.[1]

Dosage[1]

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

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

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (cont'd)

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

Code	Description
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

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 NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.[1,2]

Dosage[1,2]

Recommended IMFINZI + IMJUDO dosage for mNSCLC	Duration of therapy
For patients with body weight of ≥30 kg: **Cycles 1-4 (Q3W):** • Platinum-based chemotherapy* • IMFINZI 1500 mg • IMJUDO 75 mg† **Cycles 5 and later (Q4W):** • IMFINZI 1500 mg as a single agent until disease progression or intolerable toxicity and optional histology-based pemetrexed maintenance* • 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 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):** • IMFINZI 20 mg/kg as a single agent until disease progression or intolerable toxicity and optional histology-based pemetrexed maintenance* • 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]

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

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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
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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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 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 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
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

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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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 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 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.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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 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 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.

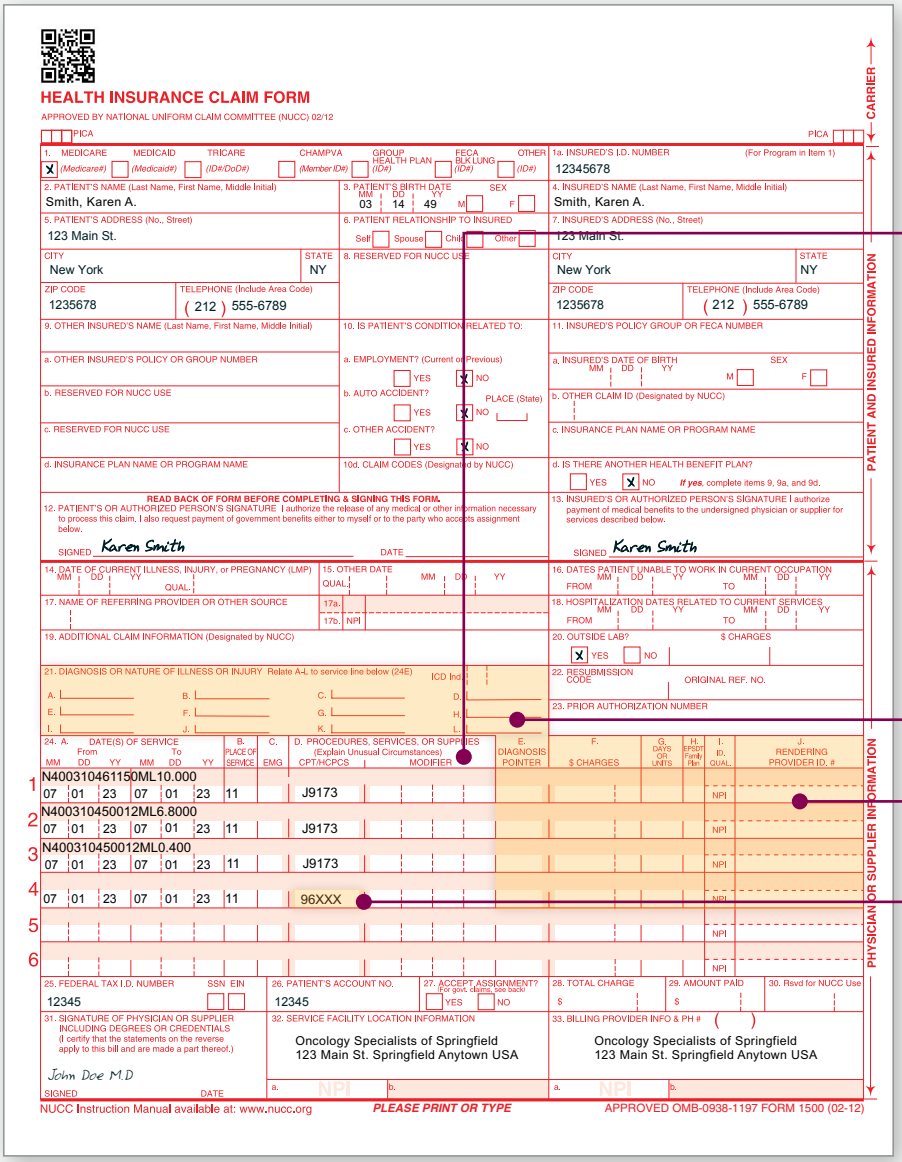
It is important to note that the codes identified in this resource are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of these codes does not guarantee reimbursement.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (cont'd)

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 (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

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

5. PATIENT'S ADDRESS (No., Street): 123 Main St.

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

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

CITY: New York | STATE: NY

8. RESERVED FOR NUCC USE

CITY: New York | STATE: NY

ZIP CODE: 1235678 | TELEPHONE (Include Area Code): (212) 555-6789

ZIP CODE: 1235678 | 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: 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 | [X] 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	N400310461150ML10.000										
	07 01 23	07 01 23	11		J9173					NPI	
2	N400310450012ML6.8000										
	07 01 23	07 01 23	11		J9173					NPI	
3	N400310450012ML0.400										
	07 01 23	07 01 23	11		J9173					NPI	
4	07 01 23	07 01 23	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.

CARRIER

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)

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.

The suggestions contained on this form are for example only and AstraZeneca makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. AstraZeneca makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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 [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): 123 Main St.

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

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

CITY: New York | STATE: NY

8. RESERVED FOR NUCC USE

CITY: New York | STATE: NY

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

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 / 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 [X] 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.

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SIGNED Karen Smith

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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? 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 N400310461150 ML30 07 01 23	07 01 23	11		J9173						NPI	
2 07 01 23	07 01 23	11		96XXX						NPI	
3 N400310453530 ML15 07 01 23	07 01 23	11		J9347						NPI	
4 07 01 23	07 01 23	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.

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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(s) and input here.

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

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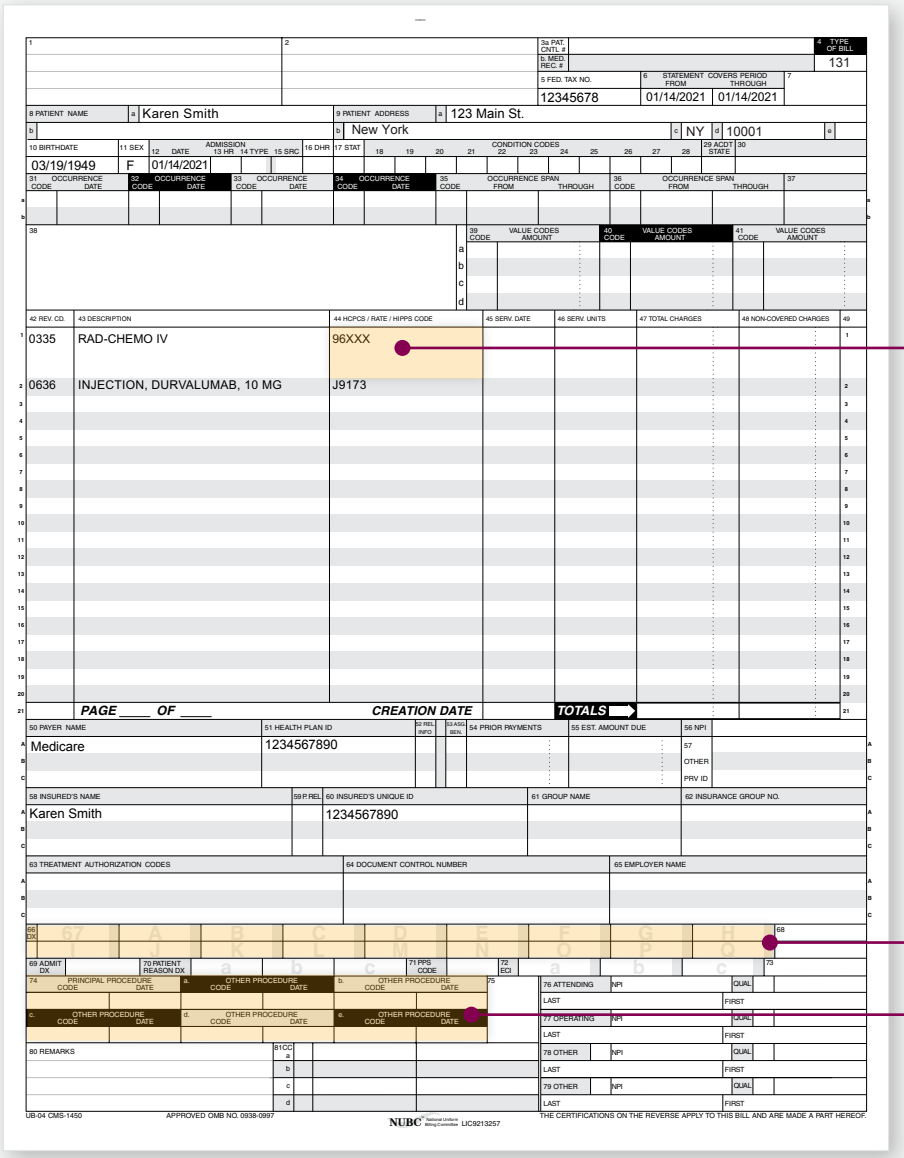
NDC=National Drug Code.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Coding, Dosage, and Wastage Guide (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				

3a PAT. CNTL. #	4 TYPE OF BILL	5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM	THROUGH
	131	12345678	01/14/2021	01/14/2021

8 PATIENT NAME	9 PATIENT ADDRESS			
Karen Smith	123 Main St.	New York	NY	10001

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT
03/19/1949	F	01/14/2021					

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		

76 ATTENDING	77 OPERATING	78 OTHER	79 OTHER
NPI / QUAL / LAST / FIRST	NPI / QUAL / LAST / FIRST	NPI / QUAL / LAST / FIRST	NPI / QUAL / LAST / FIRST

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC® National Uniform Billing Committee UC9213257 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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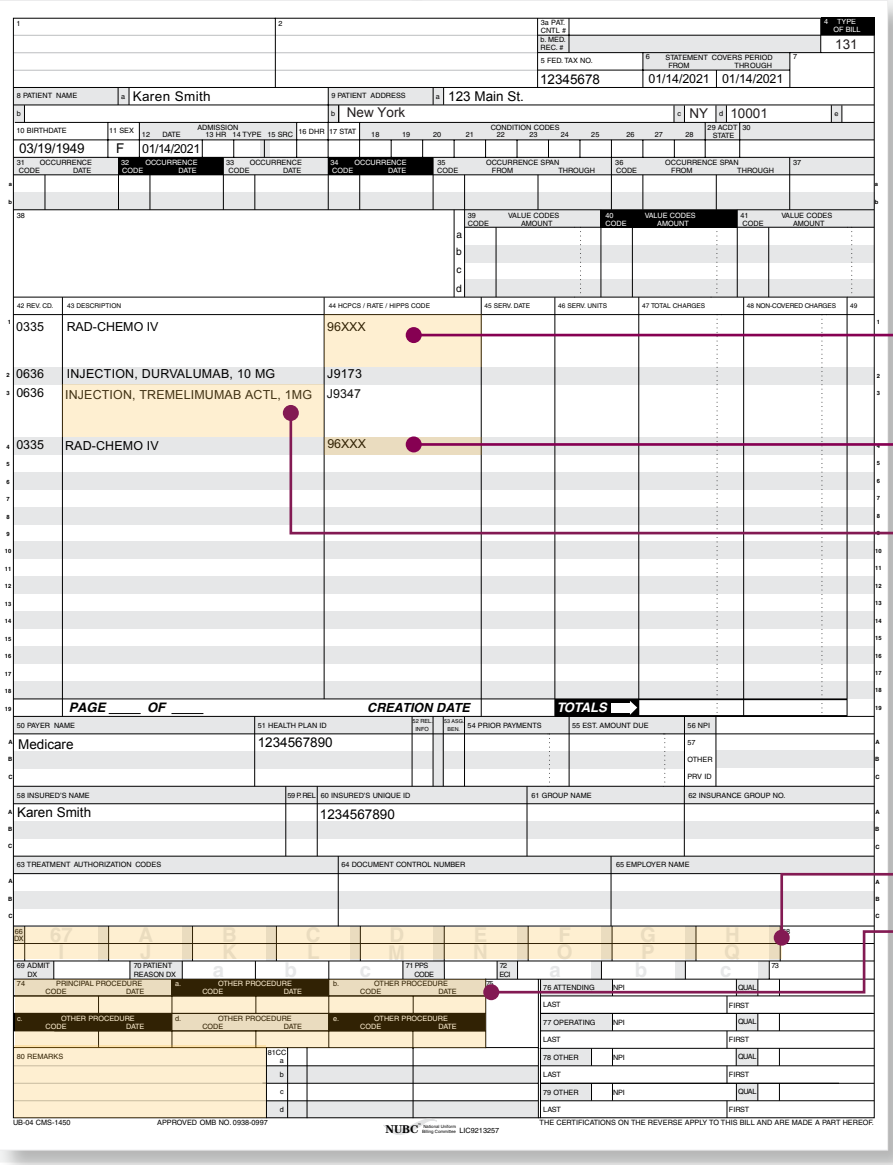
Coding, Dosage, and Wastage Guide (cont'd)

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.



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

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

Input applicable diagnosis code(s) here.

Input Place of Service codes here.

The suggestions contained on this form are for example only and AstraZeneca makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. AstraZeneca makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; NOC=not otherwise classified.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Affordability Resources

One of the goals of Access 360 is to connect patients to appropriate affordability programs. Below is information about the Patient Savings Programs and other independent foundations, including eligibility requirements.

Learn more about affordability resources for IMFINZI and/or IMJUDO.

Patient Savings Programs

For eligible, commercially insured patients

The goal of the IMFINZI and IMJUDO* Patient Savings Programs is to assist eligible, commercially insured patients with their out-of-pocket costs for IMFINZI and/or IMJUDO.

Most eligible patients will pay as little as $0 per infusion to assist with IMFINZI and/or IMJUDO out-of-pocket costs.

The annual benefit can be used for the cost of the drug itself and can also cover up to $100 in infusion costs per administration.† There are no income requirements to participate in the program.

For additional information, please visit **www.azpatientsupport.com** or call Access 360 at **1-844-ASK-A360** (1-844-275-2360).

Eligibility requirements:

- Must be a resident of the United States or Puerto Rico
- Patients must have commercial health insurance that covers medication costs for IMFINZI and/or IMJUDO, but not the full cost to the patient

Patients are ineligible if prescriptions are paid for by any state or other federally funded programs, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA or TRICARE, or where prohibited by law. Eligibility rules apply. Additional restrictions may apply.

The IMFINZI and IMJUDO Patient Savings Programs cover the cost of the drug and administration, but does not cover costs for office visits or any other associated costs.

Offer is invalid for claims and transactions more than 365 days from the date of service.

Patients may apply to the IMFINZI and/or IMJUDO Patient Savings Program, as applicable. Patients do not have to enroll in both programs.

*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.
†Patients who are residents of Massachusetts or Rhode Island are not eligible for infusion administration assistance.

FDA=US Food and Drug Administration; VA=Veterans Affairs.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Affordability Resources (cont'd)

AZ&Me™

AZ&ME™ AstraZeneca Prescription Savings Program

The AZ&Me Prescription Savings Program provides AstraZeneca medicines at no cost to qualifying patients.

Who can apply?

- People without health insurance
- Medicare Parts D and/or B recipients
- Those who have recently experienced a financial crisis
- Residents of the United States

Learn more about the AZ&Me Prescription Savings Program.

Other Resources for Patients Requiring Additional Assistance

AstraZeneca Access 360™ can provide information about independent foundations that may be able to assist with out-of-pocket costs.

- Access 360 does not guarantee support by independent foundations. Each foundation sets its own eligibility requirements and support determinations

Learn more about affordability resources for IMFINZI and/or IMJUDO.

Technology Resources

These technology resources are designed to help you manage your patients' care and may help streamline access to IMFINZI and/or IMJUDO.* Below is an overview of the different portals that are available to you (including the Access 360 Provider Portal).

Dial by Extension and Access 360 Email

Dial by Extension allows providers to connect directly with their Access 360 Patient Access Navigators. Currently, the dial-in line may result in some delays for providers and/or patients.

- Skip the phone menu and speak to or leave a message for the same Patient Access Navigator every time you call by dialing 1-844-275-2360 and selecting your navigator's extension

Access 360 Email allows HCPs to send emails directly to Access 360.

- Send questions to the Access 360 team via email at **Access360@AstraZeneca.com**†
- We will respond to your email promptly

Access 360 Provider Portal

The ***Access 360 Provider Portal*** simplifies the process for providers to manage access to select AstraZeneca medicines for patients online.

The portal:

- Makes it easy for you to enroll and track patient status from one location (only for Access 360 programs)
- Helps you access and enroll patients in affordability programs
- Contains advanced features, such as customizable alerts and multiple location access points
- Allows you to submit PA requests to any payer
- Notifies providers of real-time alerts and patient status updates

Visit the Access 360 Provider Portal.

*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.

†Protected health information should not be included in any email communications.

FDA=US Food and Drug Administration; HCP=healthcare provider; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Technology Resources (cont'd)

CoverMyMeds®

The CoverMyMeds portal* allows pharmacists and providers to initiate, transmit, and track the status of PA requests and to enroll in drug manufacturer resources, including Access 360.

The CoverMyMeds portal offers:

- Ease in finding the correct PA request
- Ability to submit PA requests to any payer and often receive real-time determinations
- Access to drug-specific financial assistance and support programs with the enrollment process for Access 360 directly incorporated

Beyond the all-payer portal solution, CoverMyMeds is also integrated into 75% of EHR systems, offering electronic PA services within workflow.

Access the CoverMyMeds portal.

covermymeds®

*Available for select AstraZeneca medicines.

EHR=electronic health record; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Technology Resources (cont'd)

AstraZeneca Specialty Savings Portal

The goal of affordability programs is to make every attempt to remove cost as a barrier for patients gaining access to necessary AstraZeneca medications.

To assist with out-of-pocket costs, Patient Savings Programs are available for eligible, commercially insured patients for select AstraZeneca specialty medications.

For eligibility criteria and additional information, please visit www.AstraZenecaSpecialtySavings.com or call Access 360 at **1-844-ASK-A360** (1-844-275-2360).

The AstraZeneca Specialty Patient Savings Enrollment portal offers these benefits for providers:

- Upon successful registration into the Patient Savings Program, providers can enroll patients and have access to immediate co-pay support for eligible, commercially insured patients
- Provides product-specific online enrollment, claims submission, and reimbursement capabilities for personnel managing patient co-pay programs
- Serves as a one-stop shop for managing multiple patients, including claims status, balance information, and contact information for support

Access the AstraZeneca Specialty Savings portal.

AstraZeneca | AstraZeneca Specialty Savings Portal

Prior Authorization and Appeal Checklists

The Prior Authorization and Appeal Checklists are designed to help simplify the PA and denial/appeal processes and should be used as a reference to ensure you have all the necessary items prior to submitting a PA or an appeal. The PA Checklist should be used after you have enrolled your patient but before you have submitted the PA to their insurance. The Appeal Checklist should be used if the PA was denied.

Download the Prior Authorization and Appeal Checklists from MyAccess360.com.

PA Checklist

The items below may be necessary to obtain a PA decision from a health plan. Please ensure you have all information below prior to submitting the PA.

☐ Completed PA request form (some health plans require specific forms)

Include the following:

- ○ Patient name, insurance policy number, and date of birth
- ○ Physician name and tax ID number
- ○ Facility name and tax ID number
- ○ Date of service
- ○ Patient diagnosis (ICD-10 code[s])
- ○ Relevant procedure and HCPCS codes for services/products to be performed/provided
- ○ Product NDC
- ○ Setting of care

☐ Letter of medical necessity and relevant clinical support

- ○ Include the Provider ID number in the letter

Download the Sample Letter of Medical Necessity from MyAccess360.com.

☐ Documentation that supports the treatment decision, such as:

- ○ Previous treatments/therapies
- ○ Patient-specific clinical notes detailing the relevant diagnosis
- ○ Relevant laboratory results
- ○ Product Prescribing Information

PA requirements vary by health plan and may require preapproval. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain a PA can result in nonpayment by the plan.*

Prior to submission, please keep track of dates and methods of correspondence (phone, email, and written); record the names of insurance contacts and reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

*Providers and patients are encouraged to contact the patient's insurer for detailed instructions on completing a PA or appealing/overturning a denial.

HCPCS=Healthcare Common Procedure Coding System; ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Prior Authorization and Appeal Checklists (cont'd)

Download the Prior Authorization and Appeal Checklists from MyAccess360.com.

Denial and Appeal Checklist

If the health plan denied a PA for an AstraZeneca medicine:

- ☐ **Review the denial notification** to understand the reason and circumstances that need to be addressed and explained in the appeal letter
- ☐ **Understand the plan's most recent explanation of benefits (EOB)** or contact a representative at the insurer to verify where the appeal should be sent and any deadlines
- ☐ **Write an appeal letter.** If you need additional information regarding this process, please contact Access 360 for examples

Download the Sample Letter of Appeal from MyAccess360.com.

If you or your patient has not received a decision within 30 days:

- ☐ **Follow up with the health plan.** Confirm the appeal letter was received and ask about its status. If the coverage denial was upheld, you could resubmit another appeal with new information or ask for a supervisor or manager to assist

If the denial is upheld again:

- ☐ **Ask for a onetime exception or a peer-to-peer medical review, or consider filing a complaint** with the state's insurance commissioner
- ☐ **If the insurer continues to deny the claim,** your patient may request an external appeal (the process varies by state law), in which an independent third party will review the claim and make a final, binding decision
- ☐ **Please contact your FRM** or Access 360 if you need additional support

FRM=Field Reimbursement Manager; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Peer-to-Peer Resource

If your patient is denied IMFINZI and/or IMJUDO,* there is an option to ask for a peer-to-peer review between you and the payer. Below are some tips to help you prepare for your meeting and help you understand what to expect.

Download the Peer-to-Peer Resource from MyAccess360.com.

What to Prepare Before Your Meeting:

Confirm the meeting date and time, gather all required documentation, and prepare to thoroughly support your treatment decision rationale.

Please note: Your peer reviewer may work within a different specialty.

☐ Gather and review documentation previously provided to payer

Include the following:

- ○ Patient clinical documentation: Case notes, date(s) of service, treatment history, laboratory results, etc
- ○ Claim form and EOB, if claim was submitted
- ○ PA request
- ○ Letter of medical necessity
- ○ Payer denial letter(s)
- ○ Letter of appeal

What to Expect During Your Meeting:

Prepare to provide/discuss the following resources:

☐ Drug information

- ○ Brand and established name
- ○ Relevant NDC number(s)
- ○ Prescribing Information
- ○ Dosing and administration
- ○ ICD-10-CM codes
- ○ Relevant HCPCS code(s) – miscellaneous or permanent J-codes, depending on the medication's approval status

☐ Literature supporting your decision to prescribe a medication

- ○ Relevant clinical guidelines
- ○ Peer-reviewed journal articles
- ○ Comparison of listings

☐ Next steps

- ○ Confirm timing for approval
- ○ Note any required follow-up steps

*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.

EOB=explanation of benefits; FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code; PA=prior authorization.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Distribution Card

Download the Distribution Card from MyAccess360.com.

Specialty Pharmacy Providers (SPPs)

IMFINZI and/or IMJUDO* is available to order from these authorized SPPs, who also provide support to help patients with their prescribed treatments:

Specialty Pharmacy	Phone	Fax	Website
ACCREDO HEALTH GROUP INC.	1-877-732-3431	1-877-251-9299	www.accredo.com
BIOLOGICS	1-800-850-4306	1-800-823-4506	https://biologics.mckesson.com
CENTERWELL†	1-800-486-2668	1-877-405-7940	www.centerwellpharmacy.com
CVS SPECIALTY‡	1-888-280-1193	1-800-323-2445	https://www.cvsspecialty.com/
ONCO360	1-877-662-6633	1-877-662-6355	www.onco360.com
OPTUM§	1-855-427-4682	1-877-342-4596	https://specialty.optumrx.com

*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.
†Effective June 2022, Humana Specialty Pharmacy was renamed to CenterWell Specialty Pharmacy.
‡US Bioservices is now part of CVS Specialty.
§Avella and Diplomat specialty pharmacies are now part of Optum Specialty Pharmacy.

Specialty Distributors

IMFINZI and/or IMJUDO is available for purchase from these authorized specialty distributors:

Specialty Distributors	Phone	Fax	Website
AMERISOURCEBERGEN			
ASD Healthcare	1-800-746-6273	1-800-547-9413	www.asdhealthcare.com
Oncology Supply	1-800-633-7555	1-800-248-8205	www.oncologysupply.com
CARDINAL HEALTH SPECIALTY DISTRIBUTION	1-855-740-1871	1-888-345-4916	http://specialtyonline.cardinalhealth.com
CURASCRIPT SD	1-877-599-7748	1-800-862-6208	www.curascriptsd.com
McKESSON SPECIALTY			
McKesson Specialty Health (MD Offices)	1-800-482-6700	1-800-289-9285	https://mscs.mckesson.com
McKesson Plasma and Biologics (Hospitals, IDNs, VA)	1-877-625-2566	1-888-752-7626	www.mckesson.com/plasmabiologics

FDA=US Food and Drug Administration; IDN=integrated delivery network; VA=Veterans Affairs.

Please see Important Safety Information on pages 30-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information

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

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. 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.

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.
  - 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.
- ***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 on pages 31-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (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.

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.
- ***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.
- ***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.
  - ***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.
  - ***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.
  - ***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.
- ***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.
- ***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.
  - ***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.
    - 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 on pages 30 and 32-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (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.
  - ***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.
- ***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.

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.

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.
- ***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.

Please see additional Important Safety Information on pages 30-31 and 33-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

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 rheumatic.
- ***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.

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 10 (2.6%) 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. 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.

Please see additional Important Safety Information on pages 30-32 and 34-35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

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

- 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.
- 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.
- 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.
- In patients with locally advanced or metastatic BTC 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 BTC 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).
- 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%).

Please see additional Important Safety Information on pages 30-33 and 35 and Full Prescribing Information including Medication Guide for IMFINZI and IMJUDO.

Important Safety Information (cont'd)

Adverse Reactions (cont'd)

- 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 IMJUDO in combination with durvalumab, 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.

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

Indications:

IMFINZI 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.

IMFINZI, in combination with IMJUDO and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

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).

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

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References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **2.** IMJUDO® (tremelimumab-actl) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **3.** CPT codes, descriptions and other data only are copyright 2023 American Medical Association. All rights reserved. **4.** Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **5.** EncoderPro for Payers Professional; Copyright ©2023 Thomson MICROMEDEX. All rights reserved. **6.** Centers for Medicare & Medicaid Services. Place of service code set (updated September 2021). Accessed August 3, 2023. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set **7.** Noridian Healthcare Solutions. Revenue codes. Accessed December 13, 2023. https://med.noridianmedicare.com/web/jea/topics/ claim-submission/revenue-codes **8.** Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. Accessed December 13, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm