IMFINZI® (durvalumab) Access & Reimbursement Guide

Information for dosing, distribution, support services, and reimbursement
Helping Patients Access The Care They Need

For assistance please call your AstraZeneca Access 360™ Reimbursement Counselor at 1-844-275-2360, 8 AM to 8 PM ET, Monday-Friday, or visit www.MyAccess360.com
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Please see Important Safety Information throughout this brochure
Product Information

Indications

IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- have disease progression during or following platinum-containing chemotherapy.
- have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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

Important Safety Information

There are no contraindications for IMFINZI® (durvalumab).

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

Please see additional Important Safety Information throughout this brochure
Dosing

Recommended Dosage for Urothelial Carcinoma
The recommended dose of IMFINZI is 10 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

Recommended Dosage for NSCLC
The recommended dose of IMFINZI is 10 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression, unacceptable toxicity, or a maximum of 12 months.

No dose reductions of IMFINZI are recommended.

IMFINZI is supplied in a carton containing one single-dose vial either as:

<table>
<thead>
<tr>
<th>IMFINZI</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 mg in 2.4 mL of solution for infusion in a single-use vial</td>
<td>0310-4500-12 (10 digit) 00310-4500-12 (11 digit)</td>
</tr>
<tr>
<td>500 mg in 10 mL of solution for infusion in a single-use vial</td>
<td>0310-4611-50 (10 digit) 00310-4611-50 (11 digit)</td>
</tr>
</tbody>
</table>

Storage Information
- Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light
- Do not freeze. Do not shake

See page 6 for complete dose preparation, administration, and storage information

For assistance please call the AstraZeneca Access 360 team at 1-844-275-2360 or visit www.MyAccess360.com
**Product Information**

**Identify Patient Dose and Vials**

*(Note that Infusion Pharmacy/Facility may have their own rounding rules for dosing):*

1. Calculate total dose in mg needed
   - a. 10 mg/kg x patient weight kg = total mg
2. Calculate number of single-use vials needed based on total dosage
   - a. Total mg/120 or 500 mg IMFINZI = total of 120 mg vials or 500 mg vials
   - b. Examples:

<table>
<thead>
<tr>
<th>Patient Weight</th>
<th>IMFINZI Dose</th>
<th>Total Dose</th>
<th>Suggested Vials Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>54 kg (120 lbs)</td>
<td>10 mg/kg</td>
<td>540 mg</td>
<td>5x 120 mg</td>
</tr>
<tr>
<td>73 kg (160 lbs)</td>
<td>10 mg/kg</td>
<td>730 mg</td>
<td>2x 120 mg + 1x 500 mg</td>
</tr>
<tr>
<td>91 kg (200 lbs)</td>
<td>10 mg/kg</td>
<td>910 mg</td>
<td>4x 120 mg + 1x 500 mg</td>
</tr>
<tr>
<td>109 kg (240 lbs)</td>
<td>10 mg/kg</td>
<td>1090 mg</td>
<td>5x 120 mg + 1x 500 mg</td>
</tr>
</tbody>
</table>

**Important Safety Information (Continued)**

**Immune-Mediated Pneumonitis**

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

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, pneumonitis occurred in 5% of patients, including Grade 3 (0.8%), Grade 4 (<0.1%), and Grade 5 (0.3%) pneumonitis. Pneumonitis led to discontinuation of IMFINZI in 1.5% of the 1889 patients. The incidence of pneumonitis (including radiation pneumonitis) was higher in patients in the PACIFIC study who completed treatment with definitive chemoradiation within 42 days prior to initiation of IMFINZI (34%) compared to patients in other clinical studies (2.3%) in which radiation therapy was generally not administered immediately prior to initiation of IMFINZI. In the PACIFIC study, the incidence of Grade 3 pneumonitis was 3.4% and of Grade 5 pneumonitis was 1.1% in the IMFINZI arm. In the PACIFIC study, pneumonitis led to discontinuation of IMFINZI in 6% of patients.

*Please see additional Important Safety Information throughout this brochure*
**Least Amount of Wastage Chart**

Example:
- Patient weighs 83.91 kg (185 lbs). To minimize waste, locate 84 kg in the table. You will need 3x 120 mg (look at the top row) and 1x 500 mg vials (look at the left column).
- Calculate exact dosage: 83.91 kg x 10 mg/kg = 839 mg. Use 860 mg of the product for a total dosage of 839 mg for the patient and total wastage of 21 mg.

<table>
<thead>
<tr>
<th>Patient Weight in Kg.</th>
<th>0</th>
<th>0-12</th>
<th>13-24</th>
<th>25-36</th>
<th>37-48</th>
<th>51-60</th>
<th>63-72</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0-12</td>
<td>13-24</td>
<td>25-36</td>
<td>37-48</td>
<td>51-60</td>
<td>63-72</td>
</tr>
<tr>
<td>49-50</td>
<td>61-62</td>
<td>73-74</td>
<td>75-86</td>
<td>87-98</td>
<td>101-110</td>
<td>113-122</td>
<td></td>
</tr>
</tbody>
</table>
Product Information | Administration

**Preparation**
- Visually inspect drug product for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed
- Do not shake the vial
- Withdraw the required volume from the vial(s) of IMFINZI and transfer into an intravenous (IV) bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake the solution. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL
- Discard partially used or empty vials of IMFINZI

**Administration**
- Administer infusion solution intravenously over 60 minutes through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter
- Do not co-administer other drugs through the same infusion line

**Storage of Infusion Solution**
- This product does not contain a preservative
- Administer infusion solution immediately once prepared. If infusion solution is not administered immediately and needs to be stored, the total time from vial puncture to the start of the administration should not exceed:
  - 4 hours at room temperature up to 25°C (77°F)
  - 24 hours in a refrigerator at 2°C to 8°C (36°F to 46°F)
- Do not freeze or shake
Important Safety Information (Continued)

Immune-Mediated Hepatitis

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

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

Please see additional Important Safety Information throughout this brochure
Distribution (Ordering and Returns)

Ordering
Dosing for IMFINZI is weight-based so the dose will vary by patient, and may be provided through a combination of vial sizes. See the Dosing section to identify the number of vials needed.

Specialty Distributors (SD):

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMERISOURCEBERGEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASD Healthcare</td>
<td>P: 1-800-746-6273</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F: 1-800-547-9413</td>
<td><a href="http://www.asdhealthcare.com">www.asdhealthcare.com</a></td>
</tr>
<tr>
<td>AMERISOURCEBERGEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oncology Supply</td>
<td>P: 1-800-633-7555</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F: 1-800-248-8205</td>
<td><a href="http://www.oncologysupply.com">www.oncologysupply.com</a></td>
</tr>
<tr>
<td>CARDINAL HEALTH SPECIALTY DISTRIBUTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:00 AM-8:00 PM ET, Mon-Fri</td>
<td>P: 1-855-740-1871</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F: 1-888-345-4916</td>
<td><a href="http://specialtyonline.cardinalhealth.com">http://specialtyonline.cardinalhealth.com</a></td>
</tr>
<tr>
<td>CURASCRIP SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8:00 AM-7:00 PM ET, Mon-Fri</td>
<td>P: 1-877-599-7748</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F: 1-800-862-6208</td>
<td><a href="http://www.curascriptsd.com">www.curascriptsd.com</a></td>
</tr>
<tr>
<td>MCKESSON SPECIALTY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>McKesson Specialty Health (Physician Offices)</td>
<td>P: 1-800-482-6700</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F: 1-800-289-9285</td>
<td><a href="https://mscs.mckesson.com">https://mscs.mckesson.com</a></td>
</tr>
<tr>
<td>MCKESSON SPECIALTY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>McKesson Plasma and Biologics (Hospitals, Integrated Delivery Networks, Veteran Affairs)</td>
<td>P: 1-877-625-2566</td>
<td></td>
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<tr>
<td></td>
<td>F: 1-888-752-7626</td>
<td><a href="http://www.mckesson.com/plasmabiologics">www.mckesson.com/plasmabiologics</a></td>
</tr>
</tbody>
</table>

The IMFINZI distribution program includes extended payment terms to AstraZeneca’s authorized distributors. Healthcare providers and institutions should contact their distributor to understand specific payment terms available to them from their distributor.
**Specialty Pharmacy Providers (SPP):**

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone</th>
<th>Fax</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accredo</strong></td>
<td>1-877-732-3431</td>
<td>1-877-251-9299</td>
<td><a href="http://www.accredo.com">www.accredo.com</a></td>
</tr>
<tr>
<td>8:00 AM-8:00 PM ET, Mon-Fri on call 24/7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Avella</strong></td>
<td>1-877-546-5779</td>
<td>1-877-546-5780</td>
<td><a href="http://www.avella.com">www.avella.com</a></td>
</tr>
<tr>
<td>8:00 AM-8:00 PM ET, Mon-Fri on call 24/7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Biologics</strong></td>
<td>1-800-850-4306</td>
<td>1-800-823-4506</td>
<td><a href="http://www.biologicsinc.com">www.biologicsinc.com</a></td>
</tr>
<tr>
<td>9:00 AM-6:00 PM ET, Mon-Fri on call 24/7</td>
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<tr>
<td><strong>CVS Specialty</strong></td>
<td>1-888-280-1193</td>
<td>1-800-323-2445</td>
<td><a href="http://www.cvsspecialty.com">www.cvsspecialty.com</a></td>
</tr>
<tr>
<td>8:30 AM-8:30 PM ET, Mon-Fri on call 24/7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diplomat</strong></td>
<td>1-877-977-9118</td>
<td>1-800-550-6272</td>
<td><a href="http://www.diplomat.is">www.diplomat.is</a></td>
</tr>
<tr>
<td>9:00 AM-9:00 PM ET, Mon-Fri, 9:00 AM-5:00 PM ET, Sat on call 24/7</td>
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<td></td>
</tr>
<tr>
<td><strong>US Bioservices</strong></td>
<td>1-877-757-0667</td>
<td>1-888-899-0067</td>
<td><a href="http://www.usbioservices.com">www.usbioservices.com</a></td>
</tr>
<tr>
<td>7:00 AM-7:00 PM ET, Mon-Fri on call 24/7</td>
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</tbody>
</table>

**Return Policy**

Please contact AstraZeneca Access 360™ if you have questions about returns.
Affordability and Support Services

AstraZeneca Field Reimbursement Manager
If you have questions about access and reimbursement for IMFINZI, your local Field Reimbursement Manager is available to deliver personalized customer service with education and patient access support.

Contact AstraZeneca Access 360 to be connected with your Field Reimbursement Manager at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

Important Safety Information (Continued)

Immune-Mediated Colitis

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

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

Please see additional Important Safety Information throughout this brochure
Affordability and Support Services

Coverage and Reimbursement
The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for select AstraZeneca medicines. Our reimbursement counselors help patients and providers with:

- Identifying and understanding prescription coverage, out-of-pocket costs, and pharmacy options
- Prior authorization support
- Pharmacy coordination
- Claims and appeal process support
- Providing eligibility requirement information and enrollment assistance for specialty Patient Savings Programs
- Referring patients to patient assistance programs
- Referrals to nurse assistance or educational support programs, if applicable

Our program is staffed with knowledgeable AstraZeneca Reimbursement Counselors who are available at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

For additional information, please visit www.MyAccess360.com.

Helping Patients Access The Care They Need
Affordability and Support Services

**Affordability**

**IMFINZI® (durvalumab) Patient Savings Program**

The IMFINZI Patient Savings Program assists qualified IMFINZI patients with their out-of-pocket costs for IMFINZI. Most eligible patients will pay $0 per dose and may have access to up to $26,000 per year to assist with IMFINZI out-of-pocket costs. There are no income requirements to participate in the program.

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.

**Program Rules**

- Patients must meet all eligibility criteria
- Program covers the cost of the drug and administration, and does not cover costs for office visits or any other associated costs
- Offer is invalid for claims and transactions more than 120 days from the date of service

**Important Safety Information (Continued)**

**Immune-Mediated Endocrinopathies**

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

- **Thyroid disorders**—Monitor thyroid function prior to and periodically during treatment. Initiate hormone replacement therapy or medical management of hyperthyroidism as clinically indicated. Withhold IMFINZI for Grades 2–4 hyperthyroidism, until clinically stable. Continue IMFINZI for hypothyroidism.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, hypothyroidism occurred in 11% of patients, while hyperthyroidism occurred in 7% of patients. Thyroiditis occurred in 0.9% of patients, including Grade 3 (<0.1%). Hypothyroidism was preceded by thyroiditis or hyperthyroidism in 25% of patients.

Please see additional Important Safety Information throughout this brochure
**Enrollment**
- You can enroll your patient into the Patient Savings Program via the online enrollment portal at [https://www.imfinzisavings.com](https://www.imfinzisavings.com)
- A Patient Savings Program account will be created for the eligible patient. Once enrolled, patient-specific account information will be presented in the portal for immediate use
- Call Access 360 at 1-844-275-2360 with any further questions about this program

**Savings Program Reimbursement**
To obtain timely reimbursement from the AstraZeneca Patient Savings Program you need to complete the following:
- Submit the Explanation of Benefits (EOB) from the primary payer into AstraZeneca by:
  - Portal: [https://www.imfinzisavings.com](https://www.imfinzisavings.com)
  - Fax: 1-844-329-2360
- For bundled claims you need to specify the medicine payment. Please submit the EOB and line items of what you submitted to the primary payer to document the specific medicine payment
- Claims submitted via fax are typically available to view the same day with approval status
- Complete claims will be processed, notification sent, and debit card loaded within 3-5 days. Missing information may delay processing
- If you have any questions about reimbursement from the AstraZeneca Patient Savings Program you can contact your Field Reimbursement Manager or AstraZeneca Access 360 at 1-844-275-2360

**Eligibility Requirements**
Eligible Patients:
- Are residents of US or Puerto Rico
  - Patients who are residents of Massachusetts, Michigan, Minnesota, or Rhode Island are not eligible for infusion assistance. These patients are eligible for support for the cost of the medicine itself
- Have commercial health insurance that covers medication costs for IMFINZI, but not the full cost to the patient
- Are not enrolled in any state or federally funded prescription insurance program
  - Includes, but is not limited to: Medicare Part B, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), or TriCare
- Patients who move from commercial to state or federally funded prescription insurance are not eligible
- Patients enrolled in a state or federally funded prescription insurance program may not use this Savings Card, even if the patient elects to be processed as an uninsured (cash-paying) patient

For assistance please call the AstraZeneca Access 360 team at **1-844-275-2360** or visit [www.MyAccess360.com](http://www.MyAccess360.com)
Affordability and Support Services

**AZ&Me™ Prescription Savings Program**

Eligible patients receive AstraZeneca medications at no cost

- Our programs are designed to help qualifying people without insurance and those in Medicare Part D. Specifically, we have two programs that may help you:
  - AZ&Me Prescription Savings program for people without insurance
  - AZ&Me Prescription Savings program for people with Medicare Part D

**How to apply:**

Application ([http://www.azandmeapp.com/assets/azmeapp_editform.pdf](http://www.azandmeapp.com/assets/azmeapp_editform.pdf))

- Include financial documentation and the application
- Call 1-800-AZandMe (1-800-292-6363) to determine patient eligibility; for patients that meet the eligibility requirements, a temporary fill can be provided while the application is being processed

**Eligibility:**

Patients may qualify for the AZ&Me programs if:

- Patients are US Citizens, or Green Card or Work Visa holders
- Patients meet certain household income requirements (visit [www.azandme.com](http://www.azandme.com) or call 1-800-AZandMe [1-800-292-6363] for additional details)
- For the program for people without insurance, patients do not have prescription drug coverage through private insurance or government programs
- Medicare Part D patients must have spent at least 3% of their total household income on prescription medicines through a Medicare Part D Prescription Drug Plan during the current year
- Please call 1-800-AZandMe with any questions related to your patient and their eligibility
Independent Foundation

AstraZeneca Access 360™ can refer you to 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 their own eligibility requirements and support determinations.
- Once Access 360 provides foundation contact information, talk to your doctor, who can help you apply for foundation support.
- For more information, call Access 360 or visit www.AstraZeneca-us.com/affordability for a list of foundations.
Affordability and Support Services | Patient Education

Patient Lighthouse Program

Program Highlights:
Lighthouse is a program that provides IMFINZI patients constant support through our dedicated Advocate service. Lighthouse Advocates encourage your patients to monitor their experience, including tracking any adverse events while on treatment.

Lighthouse offers patients:
• 24/7 support from medically-trained professionals, called Advocates
• Tools to help them track their symptoms
• Education on the importance of monitoring

How Lighthouse Can Help
• Helps you stay informed when necessary
• Bridges communication between you and your patients
• Encourages patients to track, monitor, and report adverse events

To learn more about the Lighthouse Program, call a Lighthouse Advocate at 1-855-LHOUSE1 (1-855-546-8731) or contact your AstraZeneca sales representative.

Important Safety Information (Continued)

Immune-Mediated Endocrinopathies (Continued)

• Adrenal insufficiency—Administer corticosteroids as clinically indicated and withhold IMFINZI until clinically stable for Grade 2 or higher adrenal insufficiency. In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, adrenal insufficiency occurred in 0.7% of patients, including Grade 3 (<0.1%) adrenal insufficiency.

Please see additional Important Safety Information throughout this brochure
Reimbursement

**Codes and Reimbursement Information**

AstraZeneca Access 360™ can help with questions you may have about coding and reimbursement. Contact our Reimbursement Counselors at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

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

**National Drug Code (NDC)**

The National Drug Code (NDC) is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. Payers may require the submission of the 11-digit NDC on health care claim forms, and electronic claims may be denied for drugs billed without a valid 11-digit NDC.

<table>
<thead>
<tr>
<th>10-digit NDC</th>
<th>11-digit NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosage</strong></td>
<td><strong>Code</strong></td>
</tr>
<tr>
<td>120 mg/2.4 mL single-dose vial</td>
<td>0310-4500-12</td>
</tr>
<tr>
<td>500 mg/10 mL single-dose vial</td>
<td>0310-4611-50</td>
</tr>
</tbody>
</table>

Important Safety Information (Continued)

**Immune-Mediated Endocrinopathies (Continued)**

- **Type 1 diabetes mellitus**—Initiate treatment with insulin as clinically indicated. Withhold IMFINZI for Grades 2–4 type 1 diabetes mellitus, until clinically stable. In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, type 1 diabetes mellitus occurred in <0.1% of patients.

Please see additional Important Safety Information throughout this brochure.
Claim NDC requirements

Reporting NDCs is required for Medicaid and Medicare/Medicaid claims. In general, NDC is reported for Healthcare Common Procedure Coding System (HCPCS) codes for physician-administered drugs to medicines and biologics. NDCs may also be reported to facilitate claims processing and may be required by payers. Accurate NDC reporting must include specific elements.

- NDC (11-digit format)
- NDC unit of measure qualifier
- NDC qualifier (N4)
- NDC units

NDC billing information must conform to the HIPAA 5010 standard and follows a specific format:

To calculate the NDC units for IMFINZI where a patient was administered 839 mg using 1x500 mg vial and 3x 120 mg vials, and IMFINZI is billed using a HCPCS miscellaneous code:

- The total dosage is 839 mg and the total amount to be billed is 860 mg
- The NDC unit of measure is ML
- Claim form NDC entry for the 860-mg dose of IMFINZI: N400310450012ML7.2 and N400310461150ML10, total dosage - 839mg

For assistance please call the AstraZeneca Access 360 team at 1-844-275-2360 or visit www.MyAccess360.com
**Healthcare Common Procedure Coding System (HCPCS)²,³**

The chart below lists potential code(s) for your reference when submitting claims for your IMFINZI patients. When submitting a claim using a HCPCS miscellaneous code, include specific information:

- Medicine name (both brand and generic)
- Total dosage and strength
- Method of administration
- 11-digit National Drug Code (NDC)
- Basis of measurement (1 unit)

Payer requirements for coding of newly approved medicines may vary, including which miscellaneous code to use.

When it is necessary to discard the remainder of the single-use vial after administering a dose to a Medicare patient, the program provides payment for the amount of medicine discarded as well as the dose administered, up to the amount of the medicine as indicated on the package label.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICIAN OFFICE</td>
<td></td>
</tr>
<tr>
<td>J9999</td>
<td>Not otherwise classified, antineoplastic drugs</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
<tr>
<td>HOSPITAL OUTPATIENT</td>
<td></td>
</tr>
<tr>
<td>C9492</td>
<td>Injection, Durvalumab, 10 mg</td>
</tr>
</tbody>
</table>

**Important Safety Information (Continued)**

**Immune-Mediated Endocrinopathies (Continued)**

- **Hypophysitis**—Administer corticosteroids and hormone replacement as clinically indicated and withhold IMFINZI until clinically stable for Grade 2 or higher hypophysitis. Hypopituitarism leading to adrenal insufficiency and diabetes insipidus occurred in <0.1% of 1889 patients with various cancers who received IMFINZI.

Please see additional Important Safety Information throughout this brochure

The chart below lists the potential Current Procedural Terminology (CPT) codes for your reference when submitting claims for your IMFINZI patients.

CMS has a policy for reporting the add-on infusion codes when less than a full hour of service is provided, CPT code 96415 (for “each additional hour”) is to be used for “infusion intervals of greater than thirty minutes beyond one hour increments.” If the incremental amount of infusion time is 30 minutes or less, the time is not to be billed separately. Document infusion start and stop times in the medical record. Some payers may require reporting the actual number of minutes on claims.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96413</td>
<td>Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
</tr>
<tr>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure). [Please note: report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments]</td>
</tr>
<tr>
<td>99601</td>
<td>Home infusion/specialty drug administration, per visit (up to 2 hours)</td>
</tr>
<tr>
<td>99602</td>
<td>Each additional hour (List separately in addition to code for primary procedure) [Use 99602 in conjunction with 99601]</td>
</tr>
</tbody>
</table>
**Diagnosis Codes**\(^5\)

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

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

**NSCLC**

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C34.00</td>
<td>Malignant neoplasm of unspecified main bronchus</td>
</tr>
<tr>
<td>C34.01</td>
<td>Malignant neoplasm of right main bronchus</td>
</tr>
<tr>
<td>C34.02</td>
<td>Malignant neoplasm of left main bronchus</td>
</tr>
<tr>
<td>C34.10</td>
<td>Malignant neoplasm of upper lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.11</td>
<td>Malignant neoplasm of upper lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.12</td>
<td>Malignant neoplasm of upper lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.2</td>
<td>Malignant neoplasm of middle lobe, bronchus or lung</td>
</tr>
<tr>
<td>C34.30</td>
<td>Malignant neoplasm of lower lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.31</td>
<td>Malignant neoplasm of lower lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.32</td>
<td>Malignant neoplasm of lower lobe, left bronchus or lung</td>
</tr>
</tbody>
</table>

\(^*\)IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- have disease progression during or following platinum-containing chemotherapy.
- have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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

Please see additional Important Safety Information throughout this brochure
### Important Safety Information (Continued)
#### Immune-Mediated Nephritis
IMFINZI can cause immune-mediated nephritis, defined as evidence of renal dysfunction requiring use of corticosteroids. Fatal cases have occurred. Monitor patients for abnormal renal function tests prior to and periodically during treatment with IMFINZI. Administer corticosteroids as clinically indicated. Withhold IMFINZI for creatinine greater than 1.5 to 3 times the ULN; permanently discontinue IMFINZI and administer corticosteroids in patients with creatinine greater than 3 times the ULN.

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, nephritis (reported as any of the following: increased creatinine or urea, acute kidney injury, renal failure, decreased glomerular filtration rate, tubulointerstitial nephritis, decreased creatinine clearance, glomerulonephritis, and nephritis) occurred in 6.3% of the patients including Grade 3 (1.1%), Grade 4 (0.2%), and Grade 5 (0.1%) nephritis. IMFINZI was discontinued in 0.3% of the 1889 patients.

---

For assistance please call the AstraZeneca Access 360 team at 1-844-275-2360 or visit www.MyAccess360.com
Bladder Cancer

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of the prostate</td>
</tr>
<tr>
<td>C65.1</td>
<td>Malignant neoplasm of the right renal pelvis</td>
</tr>
<tr>
<td>C65.2</td>
<td>Malignant neoplasm of the left renal pelvis</td>
</tr>
<tr>
<td>C65.9</td>
<td>Malignant neoplasm of unspecified renal pelvis</td>
</tr>
<tr>
<td>C66.1</td>
<td>Malignant neoplasm of the right ureter</td>
</tr>
<tr>
<td>C66.2</td>
<td>Malignant neoplasm of the left ureter</td>
</tr>
<tr>
<td>C66.9</td>
<td>Malignant neoplasm of unspecified ureter</td>
</tr>
<tr>
<td>C67.0</td>
<td>Malignant neoplasm of trigone of bladder</td>
</tr>
<tr>
<td>C67.1</td>
<td>Malignant neoplasm of dome of bladder</td>
</tr>
<tr>
<td>C67.2</td>
<td>Malignant neoplasm of lateral wall of bladder</td>
</tr>
<tr>
<td>C67.3</td>
<td>Malignant neoplasm of anterior wall of bladder</td>
</tr>
<tr>
<td>C67.4</td>
<td>Malignant neoplasm of posterior wall of bladder</td>
</tr>
</tbody>
</table>

Important Safety Information (Continued)

Immune-Mediated Dermatologic Reactions

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

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

Please see additional Important Safety Information throughout this brochure
### ICD-10-CM

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C67.5</td>
<td>Malignant neoplasm of bladder neck</td>
</tr>
<tr>
<td>C67.6</td>
<td>Malignant neoplasm of ureteric orifice</td>
</tr>
<tr>
<td>C67.7</td>
<td>Malignant neoplasm of urachus</td>
</tr>
<tr>
<td>C67.8</td>
<td>Malignant neoplasm of overlapping sites of bladder</td>
</tr>
<tr>
<td>C67.9</td>
<td>Malignant neoplasm of bladder, unspecified</td>
</tr>
<tr>
<td>C68.0</td>
<td>Malignant neoplasm of urethra</td>
</tr>
<tr>
<td>D09.0</td>
<td>Carcinoma in situ of bladder</td>
</tr>
<tr>
<td>Z85.51</td>
<td>Personal history of malignant neoplasm of bladder</td>
</tr>
<tr>
<td>Z85.59</td>
<td>Personal history of malignant neoplasm of other urinary tract organ</td>
</tr>
</tbody>
</table>

### Revenue Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0258</td>
<td>IV Solutions (Pharmacy series 025X)</td>
</tr>
<tr>
<td>0263</td>
<td>Drug/supply delivery (IV Therapy series 026X)</td>
</tr>
<tr>
<td>0636</td>
<td>Drugs requiring detailed coding (Pharmacy extension series 063X)</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Location</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Office</td>
<td>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.</td>
</tr>
<tr>
<td>19</td>
<td>Off Campus: Outpatient Hospital</td>
<td>A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization. (Effective January 1, 2016)</td>
</tr>
<tr>
<td>22</td>
<td>On Campus: Outpatient Hospital</td>
<td>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. (Description change effective January 1, 2016)</td>
</tr>
</tbody>
</table>

**Important Safety Information (Continued)**

**Other Immune-Mediated Adverse Reactions**

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

Please see additional Important Safety Information throughout this brochure
Modifiers\textsuperscript{4,8-14}

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. They add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to the provision of IMFINZI\textsuperscript{®} (durvalumab) in physician offices and hospital outpatient departments.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Indication and Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO</td>
<td>Services, procedures, and/or surgeries provided at off-campus provider-based outpatient departments</td>
<td>• To be reported with every HCPCS code for all items and services furnished in off-campus provider-based departments of a hospital&lt;br&gt;• Should not be reported for remote locations or satellite facilities of a hospital, or emergency departments</td>
</tr>
<tr>
<td>JA</td>
<td>Administered intravenously</td>
<td>This modifier is informational only and may be submitted with all injection codes</td>
</tr>
<tr>
<td>JW</td>
<td>Drug or biological amount discarded/not administered to any patient</td>
<td>• Unused drug remains after applicable dose is administered from single-use vial&lt;br&gt;• CMS has issued a discarded drug policy, local MAC/other payer requirements may vary&lt;br&gt;• Payers may have different requirements how to code unused drug with miscellaneous HCPCS drug codes&lt;br&gt;• Typically the modifier is appended to the drug code on a line separate from that reporting the administered dose</td>
</tr>
<tr>
<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
<td>• Represents awareness of/compliance with payer policies for the use of specific codes&lt;br&gt;• Payer requirements may vary regarding use with the chemotherapy/complex biologic infusion codes&lt;br&gt;• Append the modifier to codes as required by the payer</td>
</tr>
</tbody>
</table>
### Modifiers (Continued)

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
<th>Indication and Placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>Infusion suite</td>
<td>Home infusion services provided in the infusion suite of the IV therapy provider</td>
</tr>
<tr>
<td>25</td>
<td>Significant, Separately Identifiable Evaluation and Management (E/M) Service by Same Physician or Other Qualified HCP on the Same Day of Procedure or Other Service</td>
<td>• Patient requires distinct E/M service in addition to the infusion procedure&lt;br&gt;• Must be substantiated with relevant documentation&lt;br&gt;• Append the modifier to the relevant E/M code</td>
</tr>
<tr>
<td>59†</td>
<td>Distinct Procedural Service</td>
<td>• Indicates a procedure or service separate and distinct from another service with which it would usually be considered bundled&lt;br&gt;• Do not use with E/M codes and use only if a more descriptive modifier is not available&lt;br&gt;• May append to an initial drug administration service code when the patient must return for a separately identifiable drug administration service on the same day or has two IV lines per protocol</td>
</tr>
<tr>
<td>XE</td>
<td>Separate Encounter</td>
<td>A service that is distinct because it has occurred during a separate encounter</td>
</tr>
<tr>
<td>XS</td>
<td>Separate Structure</td>
<td>A service that is distinct because it was performed on a separate organ/structure</td>
</tr>
<tr>
<td>XP</td>
<td>Separate Practitioner</td>
<td>A service that is distinct because it was performed by a different practitioner</td>
</tr>
<tr>
<td>XU</td>
<td>Unusual Non-overlapping Service</td>
<td>The use of a service that is distinct because it does not overlap components of the main service</td>
</tr>
</tbody>
</table>

†Although CMS continues to recognize the -59 modifier, it may selectively require a -X (EPSU) modifier, especially when billing codes are at high risk for incorrect billing. CMS encourages providers to migrate to these more specific modifiers.

### Important Safety Information (Continued)

#### Other Immune-Mediated Adverse Reactions (Continued)

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

Please see additional Important Safety Information throughout this brochure
Annotated Claims and Checklists

AstraZeneca Access 360™ can help with questions you may have about prior authorization and the claim process. Contact our Reimbursement Counselors at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

Prior Authorization Checklist

Prior authorization requirements vary by payer and may require that medicines be pre-approved. Failure to obtain preauthorization can result in non-payment by the plan. The items listed below may be necessary to obtain a prior authorization decision from a payer:

1. Completed prior authorization request form (some payers require specific forms)
   Include the following:
   • Patient information, including name, insurance policy number, and date of birth
   • Physician information, including name and tax ID number
   • Facility information, including name and tax ID number
   • Date of service
   • Patient diagnosis
   • Relevant procedure and HCPCS codes for services/products to be performed/provided
   • Product NDC
   • Setting of care
   • Patient clinical notes detailing the relevant diagnosis

2. Letter of medical necessity
   • Include the Provider ID number in the letter
Annotated Claims and Checklists

Prior Authorization Checklist (Continued)

3. Documentation that supports the treatment decision, such as:
   • Previously given treatments/therapies
   • Patient clinical notes detailing the relevant diagnosis
   • Relevant laboratory results
   • Product package insert

4. Additional relevant documentation (if available) regarding the treatment decision

Claim Submission Checklist

To prevent denials and incorrect reimbursement payments, review claim forms prior to submitting to a payer:

1. Has insurance been verified and covers the medicine and service?
2. Were the specific payer requirements followed?
3. If applicable, is the referral from a primary care provider authorized?
4. Is medical necessity documented?
5. Is all of the required information included on the claim?
6. Are the correct codes (NDC, diagnosis, CPT, HCPCS, modifiers) reported?
7. For the medicine:
   • Are the billed units accurate?
   • If reporting any discarded medicine, was it properly documented?
8. If a separate and distinct Evaluation and Management (E/M) service was provided, is it identified with modifier 25?
### Annotated Claims

#### Claim Summary Table:

<table>
<thead>
<tr>
<th>Type of Code</th>
<th>Location on CMS-1500 Form (Office)</th>
<th>Location on UB-04 Form (Hospital Outpatient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis ICD-10 CM</td>
<td>Item 21</td>
<td>Item 66</td>
</tr>
<tr>
<td>Diagnosis Pointer (letter that relates to service line)</td>
<td>Item 24E</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Procedure: IMFINZI infusion time corresponds to CPT code 96413. Some payers may prefer other codes; verify with the applicable payer</td>
<td>Item 24D</td>
<td>Item 44</td>
</tr>
<tr>
<td>Place of Service provides setting information for services provided, if delivered in outpatient hospital settings the specific off-campus or on-campus code must be used</td>
<td>Item 24B</td>
<td>Item 44 may require PO modifier</td>
</tr>
<tr>
<td>Revenue and description are included for each line item. For the line item for IMFINZI include the brand and generic names. Medicines that are billed with HCPCS codes usually require revenue code 0636.</td>
<td>Not applicable</td>
<td>Item 42 and 43</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Item 24D</td>
<td>Item 44 or electronic comment field (Field 80)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payer requirements for coding of newly approved medicines may vary, including which miscellaneous code to use. Additional information required will vary by payer.</td>
<td>Item 24D</td>
<td>Item 44 or electronic comment field (Field 80)</td>
</tr>
<tr>
<td>NDC</td>
<td>Item 19 and shaded area above line item in Field 24A or 24D</td>
<td>Item 44 or electronic comment field (Field 80)</td>
</tr>
<tr>
<td>Units – 1 unit is typically with a miscellaneous HCPCS code regardless of the dose and number of vials used</td>
<td>Item 24G</td>
<td>Item 46</td>
</tr>
</tbody>
</table>
CMS–1500
Annotated Claim Form

J9999 Code:
*Payers may require which miscellaneous code to use*

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. Providers are solely responsible for determining the billing and coding requirements applicable to any payer. 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.
UB–04
Annotated Claim Form

C9399 Code:

Payers may require which miscellaneous code to use, for example J9999 for non-Medicare patients

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For assistance please call the AstraZeneca Access 360 team at 1-844-275-2360 or visit www.MyAccess360.com
Denial Management

AstraZeneca Access 360™ can help with denial and appeal support. Contact our Reimbursement Counselors at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

Typical Reasons for Denials

Common reasons for denials or incorrect payments of claims include:

- Omission of any information that clarifies medical necessity (ie, relevant diagnosis codes)
- Omission of a physician letter/statement of medical necessity
- Inaccurately reporting the billable units of medicine
  - 1 unit is typically entered for billing when a miscellaneous medicine code is used and the total dosage administered is typically included with the NDC
- Use of incorrect CPT or HCPCS codes
- Lack of proper and complete documentation
- Omission of special coding requirements (eg, the NDC number or required modifiers)
- Failure to follow payer-specific requirements for providing a medicine

Denial Instructions

Step 1: Ensure that the prior authorization or claim was completed and submitted correctly. Prior to initiating the appeal process, it is important to identify the reason for denial, which can often be found in the explanation of benefits (EOB), as well as the specific insurer’s instructions and processes regarding the appeal process (eg, forms, information, timelines).

Step 2: If the denial reasons are due to incorrect or missing information, identify the appeal process based on payer requirements and gather the information needed.

Step 3: If the denial is due to other reasons, it may need to be appealed following payer appeal requirements.
Template Letters

Full Prescribing Information for IMFINZI can be found at www.MyAccess360.com. If additional literature or references are needed, please contact our AstraZeneca Information Center at 1-800-236-9933 (Monday - Friday, 8 AM - 6 PM ET) for all clinical and medical questions.

Letter of Medical Necessity

When third-party payers review prior authorizations or claims first they will determine if the reported service is covered under their contract or rules. Most payers cover medicine infusions as part of their core benefits. Next, payers will look for evidence supporting the medical necessity of the medicine. This evidence may include:

- Information about the patient’s medical condition and history
- A physician’s statement or letter of medical necessity
- Supporting literature (eg, peer-reviewed studies and compendia monographs)
- Prescribing Information
- Availability of other treatment alternatives

Sample Letter of Medical Necessity


Use of this letter does not guarantee that an insurance company will provide reimbursement for AstraZeneca medicines, and is not intended to be a substitute for, or an influence on, the independent medical judgment of the physician.
**Appeals**

AstraZeneca Access 360™ can help with denial and appeal support, including external reviews for patients. Contact our Reimbursement Counselors at 1-844-275-2360 Monday - Friday 8 AM-8 PM ET.

Payers have different appeal requirements that may depend upon the level of appeal required for the denied prior authorization or claim (e.g., first appeal, second appeal). In the event of a denial you should resubmit your prior authorization or claim because many well-documented follow-up submissions are successful.

Patients can help with appeal processes. You may want to encourage your patients to contact their employer’s benefits office because companies may be willing to intervene on behalf of employees when prescribed therapies are challenged. Patients can also request an external review which is a request for a reconsideration of a decision to deny payment. If a payer upholds its decision to deny payment, patients have the right to appeal the decisions to an outside, independent decision-maker, regardless of the type of insurance or state an individual lives in.

Additional resources for appealing Medicare claims may be found at: https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/index.html?redirect=/orgmedffsappeals/.

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**Sample Letter of Appeal**

*Healthcare Provider Letterhead*

Date [Date]

[Place Name] [Place Address] [City, State, ZIP Code]

[Phone Number] [Fax Number]

Patient Name [Patient Name]

Patient Date of Birth [Patient Date of Birth]

Policy Number [Policy Number]

Group Number [Group Number]

Dear [Name of the Contact Person at the Insurance Company],

I am writing on behalf of my patient, [Name of Patient], to appeal [Name of Health Insurance Company’s] decision to deny coverage for [Drug Name] which is prescribed to treat [reason for prescription]. [Reason for denial] [reason for denial]. The coverage has been denied for the following reason(s), [List the Specific Reason(s) for the Denial as Stated in the Denial Letter].

Patient History and Diagnosis

[Provide a Brief Description of the Patient’s Medical Condition Here]

[Include a Brief Summary of the Patient’s Medical History]

[Explain why you believe it is medically necessary for the patient to receive the medication]

[Describe the Potential Consequences of the Patient if they do not receive the medication]

[Attach and Attach Supporting Letters of Medical Necessity from any Specialist that is or has provided care to the patient]

[Include Medical Indication Information]

[Include Medicine Administration Information]

Thank you in advance for your immediate attention to this written appeal.

Sincerely,

[Physician’s Name]

[Physician’s Practice Name]

References

[Include medicine PIs]

[Include other relevant references and publications regarding medicine]

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|| Use of this letter does not guarantee that an insurance company will provide reimbursement for AstraZeneca medicines, and is not intended to be a substitute for, or an influence on, the independent medical judgment of the physician.

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**Sample Letter of Appeal**

**Appeal Instructions**

**Step 1:** Ensure that the prior authorization or claim was completed and submitted correctly. Prior to initiating the appeal process, it is important to identify the reason for denial, which can often be found in the explanation of benefits (EOB), as well as the specific insurer’s instructions and processes regarding the appeal process (eg, forms, information, timelines).

**Step 2:** Identify the appeal process based on payer requirements and gather the information needed.

**Step 3:** Complete the appeal submission process. A template is below for healthcare providers to use when responding to coverage denial from patients’ health insurance companies. Providers should provide the items listed below to the payer when submitting an appeal. Failure to do so may result in another denial.

1. **Formal letter appealing the denial**
   - It is good practice to write the appeal letter on practice letterhead. If one is unavailable, then healthcare providers should enter all of their contact information at the top of the appeal letter

2. **Letter of Medical Necessity**
   - Include the proposed treatment plan and the Provider ID number in the letter

3. **A Copy of Denial/Explanation of Benefits (EOB) that details the reason for the denial**

4. **Clinical Notes and other relevant documentation regarding treatment decisions, such as:**
   - Previously tried treatments/therapies and other relevant medical history
   - Patient clinical notes detailing the relevant diagnosis
   - Relevant laboratory results
   - Product package insert

5. **Any other additional supporting documents**
References

Important Safety Information (Continued)

Infection

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

In clinical studies enrolling 1889 patients with various cancers who received IMFINZI, infections occurred in 43% of patients, including Grade 3 (8%), Grade 4 (1.9%), and Grade 5 (1.0%). The overall incidence of infections in IMFINZI-treated patients in the PACIFIC study (56%) was higher compared to patients in other clinical studies (38%) in which radiation therapy was generally not administered immediately prior to initiation of IMFINZI. In patients with UC in Study 1108 (n=182), the most common Grade 3 or higher infection was urinary tract infections, which occurred in 4% of patients. In patients with Stage III NSCLC in the PACIFIC study, the most common Grade 3 or higher infection was pneumonia, which occurred in 5% of patients.

Infusion-Related Reactions

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

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

Embryo-Fetal Toxicity

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

Lactation

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

Important Safety Information continued on next page
Important Safety Information (Continued)

Most Common Adverse Reactions

- In patients with UC in Study 1108 (n=182), the most common adverse reactions (≥15%) were fatigue (39%), musculoskeletal pain (24%), constipation (21%), decreased appetite (19%), nausea (16%), peripheral edema (15%), and urinary tract infection (15%). The most common Grade 3 or 4 adverse reactions (≥3%) were fatigue, urinary tract infection, musculoskeletal pain, abdominal pain, dehydration, and general physical health deterioration.

- In patients with UC in Study 1108, discontinuation due to adverse reactions occurred in 3.3% of patients. Serious adverse reactions occurred in 46% of patients. The most frequent serious adverse reactions (>2%) were acute kidney injury (4.9%), urinary tract infection (4.4%), musculoskeletal pain (4.4%), liver injury (3.3%), general physical health deterioration (3.3%), sepsis, abdominal pain, and pyrexia/tumor associated fever (2.7% each).

- In patients with Stage III NSCLC in the PACIFIC study (IMFINZI n=475), the most common adverse reactions (≥20% of patients) were cough (40%), fatigue (34%), pneumonitis or radiation pneumonitis (34%), upper respiratory tract infections (26%), dyspnea (25%), and rash (23%). The most common Grade 3 or 4 adverse reaction (≥3%) was pneumonia (7%).

- In patients with Stage III NSCLC in the PACIFIC study (IMFINZI n=475), discontinuation due to adverse reactions occurred in 15% of patients in the IMFINZI arm. Serious adverse reactions occurred in 29% of patients receiving IMFINZI. The most frequent serious adverse reactions (≥2% of patients) were pneumonitis or radiation pneumonitis (7%) and pneumonia (6%). Fatal pneumonitis or radiation pneumonitis and fatal pneumonia occurred in <2% of patients and were similar across arms.

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

Please see accompanying complete Prescribing Information, including Medication Guide.
Helping Patients Access The Care They Need
Connecting with AstraZeneca Access 360™ is easy:

1-844-ASK-A360 (1-844-275-2360)  
1-844-FAX-A360 (1-844-329-2360)  
www.MyAccess360.com

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