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| TODAY’S DATE: | [MONTH DAY, YEAR] |
| TO: | NADs, NOADs, and ADORAs |
| FROM: | IO Access Strategy Team – Cheryl Chia |
| SUBJECT: | Sample Order Set Template |
| WHY ARE YOU RECEIVING THIS: | The Sample Order Set Template will help NADs, NOADs, and ADORAs proactively share the type of information needed for EMR Order Sets.  NOADs and ADORAs may also use the Sample Order Set Template to reactively address healthcare questions from EMR users about the type of information included in an EMR Order Set based on triaged requests from OASs or OBMs on behalf of non-NOAD accounts. |
| DO: | NADs, NOADs, and ADORAs: Use the Sample Order Set Template to proactively share the type of information needed for EMR Order Sets.  NOADs and ADORAs: Use the Sample Order Set Template to reactively address healthcare questions from EMR users about the type of information included in an EMR Order Set based on triaged requests from OASs or OBMs on behalf of non-NOAD accounts.  The NAD/NOAD/ADORA will be present at the meeting, but if Medical is not present, refer questions to Medical Information via an MIR.  The AstraZeneca Information Center can be reached at 1-800-236-9933. |
| WHO: | EMR users at the institution or health system; EMR users, Medical Directors, and Pharmacy Directors who have decision-making responsibilities for access to therapy. |
| MUST: | EMR users can independently transfer the information to their specific order set, if necessary. The Sample Order Set Template will be delivered by NADs, NOADs, and ADORAs as separate and distinct examples from any branded discussions. |
| DO NOT: | • Do not discuss AstraZeneca products or new uses that are not FDA approved  • Do not assist EMR users with implementing the order set into their system |
| FOR MORE INFORMATION CONTACT: | If you have any questions regarding this information or about communicating with your customer, please discuss with your Manager or contact Cheryl Chia at Cheryl.Chia@astrazeneca.com. |

ADORA=Associate Director of Oncology Regional Accounts; EMR=electronic medical record; FDA=US Food and Drug Administration; IO=immuno-oncology; MIR=medical information request; NAD=National Account Director; NOAD=National Oncology Account Director; OAS=Oncology Account Specialist; OBM=Oncology Business Manager; RAD=Regional Account Director.

IMFINZI® (durvalumab) + NEOADJUVANT CHEMOTHERAPY FOLLOWED BY ADJUVANT IMFINZI SAMPLE ORDER SET FOR RESECTABLE (TUMORS ≥4 CM AND/OR NODE POSITIVE) NON-SMALL CELL LUNG CANCER

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This document is an example of an order set for the implementation of IMFINZI in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by IMFINZI continued as a single agent as adjuvant treatment after surgery, in adult patients with resectable (tumors ≥4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements into electronic medical record (EMR) systems.1 Please modify as needed to meet institutional standards.

**Please see additional Important Safety Information on pages 6-10 and complete Prescribing Information, including Medication Guide, for** [**IMFINZI**](https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/9496217c-08b3-432b-ab4f-538d795820bd/9496217c-08b3-432b-ab4f-538d795820bd_viewable_rendition__v.pdf)**.**

**Neoadjuvant Durvalumab and Carboplatin or Cisplatin followed by Adjuvant Durvalumab**

ALT=alanine aminotransferase; AST=aspartate aminotransferase; CBC=complete blood count; LFT=liver function tests; NSCLC=non-small cell lung cancer; Q3W=every three weeks; Q4W=every four weeks; T3=triiodothyronine; T4=thyroxine; TSH=thyroid stimulating hormone; ULN=upper limit normal.

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| **Laboratory Studies1,2** (Please use medical judgment on which labs to select based on the following information.) | | | |
| **Study** | **Frequency** | | **Comment/Parameters** |
| **CBC with differential** | Baseline, Q3W, then within 30 days before surgery. Post-surgery, Q4W.  Hematology assessments may be performed more frequently if clinically indicated. | |  |
| **Clinical chemistry** | Baseline, Q3W, then within 30 days before surgery. Post-surgery, Q4W.  Serum or plasma clinical chemistry assessments may be performed more frequently if clinically indicated. | | Recommended to have creatinine clearance >40 mL/min or as determined by Cockcroft-Gault equation using actual body weight. |
| **Liver panel**  **(bilirubin, LFTs)** | Baseline, then as clinically indicated until surgery. Post-surgery, initial dose, then as clinically indicated for Q4W. | | Recommended to have total bilirubin ≤1.5 × ULN,  ALT and AST ≤2.5 × ULN. |
| **Thyroid panel**  **(TSH, free T3, free T4)** | Baseline, then as clinically indicated until surgery. Post-surgery, initial dose, then as clinically indicated for Q4W. | | Free T3 or Free T4 will only be measured if TSH is abnormal or if there is clinical suspicion of an adverse event related to the endocrine system. |
| **Urine pregnancy**  **test** | Baseline, then Q3W. Post-surgery, Q4W. | | Advise females of reproductive potential to use effective contraception during treatment with IMFINZI and for 3 months after the last dose of IMFINZI. |
| **Other monitoring** | Baseline, Q3W, then within 30 days before surgery. Post-surgery, Q4W. | | Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Signs and symptoms include pneumonitis, rash, hepatitis, endocrinopathies, hypophysitis, hyperglycemia or other signs and symptoms of diabetes, thyroid disorders, thyroiditis, hyperthyroidism, nephritis with renal dysfunction, dermatology reactions, pancreatitis, and other immune-mediated adverse reactions. |
| **Treatment Conditions and Parameters1** | | | | | |
| **Recommended hold/discontinuation parameters**  Please see complete Prescribing Information for additional information regarding therapeutic interventions | | | No dose reduction for IMFINZI is recommended. In general, withhold IMFINZI for severe **(Grade 3)** immune-mediated adverse reactions. Permanently discontinue IMFINZI for life-threatening **(Grade 4)** immune-mediated adverse reactions, recurrent severe **(Grade 3)** immune-mediated reactions that require systemic immunosuppressive treatment or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids.  Dosage modifications for IMFINZI or IMFINZI in combination with chemotherapy for adverse reactions that require management different from these general guidelines summarized below:  **Pneumonitis:** For **Grade 2**, withhold until complete or partial resolution (**Grade 0 to 1)** after corticosteroid taper\*; for **Grade 3 or 4**, permanently discontinue.  **Colitis:** For **Grade 2**, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; for **Grade 3** withhold until complete or partial resolution (**Grade 0 to 1)** after corticosteroid taper\* or permanently discontinue; for **Grade 4** permanently discontinue.  **Intestinal perforation:** For any grade, permanently discontinue.  **Hepatitis with no tumor involvement of the liver:** For ALT or AST increases to more than 3 and up to 8 times the ULN or total bilirubin increases to more than 1.5 and up to 3 times ULN, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; for ALT or AST increases to more than 8 times ULN or bilirubin increases to more than 3 times the ULN, permanently discontinue.  **Hepatitis with tumor involvement of the liver**†**:** For ALT or AST increases to more than 1 and up to 3 times the ULN at baseline and increases to more than 5 and up to 10 times ULN or AST or ALT is more than 3 and up to 5 times ULN at baseline and increases to more than 8 and up to 10 times ULN, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; for AST or ALT increases to more than 10 times ULN or total bilirubin increases to more than 3 times the ULN, permanently discontinue.  **Endocrinopathies:** For **Grade 3 or 4**, withhold until clinically stable or permanently discontinue depending on severity.  **Nephritis with renal dysfunction:** For **Grade 2 or 3** increased blood creatinine, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; for Grade 4 increased blood creatinine, permanently discontinue.  **Exfoliative dermatologic conditions:** For suspected SJS, TEN, or DRESS, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; if confirmed SJS, TEN, or DRESS, permanently discontinue.  **Myocarditis:** For **Grade 2, 3, or 4**, permanently discontinue.  **Neurological toxicities:** For **Grade 2**, withhold until complete or partial resolution **(Grade 0 to 1)** after corticosteroid taper\*; for **Grade 3 or 4**, permanently discontinue.  **Infusion-related reactions:** For **Grade 1 or 2**, interrupt or slow the rate of infusion; for **Grade 3 or 4** permanently discontinue. | | |

\*Permanently discontinue if there is no complete or partial resolution with 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.1

†If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.1

DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; SJS=Steven Johnson Syndrome; TEN=toxic epidermal necrolysis.

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| **Prehydration and Premedications** | |
| Prehydration | **For Durvalumab:** Per institution-preferred protocol  **For Chemotherapy:** Per institution-preferred protocol |
| Premedications | **For Durvalumab:** Per institution-preferred protocol  **For Chemotherapy:** Per institution-preferred protocol |

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| **Chemotherapy Orders1** | |
| Cycle 1-4; cycle length=3 weeks | |
| **For patients with a body weight of ≥30 kg:**  Neoadjuvant: Durvalumab 1500 mg in combination with chemotherapy\* Q3W for up to 4 cycles prior to surgery  **For patients with a body weight of <30 kg:**  Neoadjuvant: Durvalumab 20 mg/kg Q3W in combination with chemotherapy for up to 4 cycles prior to surgery | **Durvalumab:** Dilute to final concentration 1 mg/mL to 15 mg/mL with 0.9% sodium chloride injection, USP or 5% dextrose injection, USP and administer over 60 minutes. Use sterile, low protein binding 0.2 or 0.22 micron in-line filter. Administer infusion solution immediately once prepared. The total time from vial preparation to the completion of infusion should not exceed 28 days in a refrigerator (2 °C to 8 °C) or 8 hours at room temperature (up to 25 °C). Discard partially used or empty vials of IMFINZI. Do not co-administer other drugs through the same infusion line.  **Chemotherapy:** Administer per institution-preferred protocol following administration of durvalumab. |
| Cycle 5 and beyond (until disease progression prior to surgery, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery); cycle length=4 weeks | |
| **For patients with a body weight of ≥30 kg:** Adjuvant:Durvalumab 1500 mg as a single agent Q4W for up to 12 cycles after surgery  **For patients with a body weight of <30 kg:**  Adjuvant:Durvalumab 20 mg/kg Q4W as a single agent up to 12 cycles after surgery | **Durvalumab:** Dilute to final concentration 1 mg/mL to 15 mg/mL with 0.9% sodium chloride injection, USP or 5% dextrose injection, USP and administer over 60 minutes. Use sterile, low protein binding 0.2 or 0.22 micron in-line filter. Administer infusion solution immediately once prepared. The total time from vial preparation to the completion of infusion should not exceed 28 days in a refrigerator (2 °C to 8 °C) or 8 hours at room temperature (up to 25 °C). Discard partially used or empty vials of IMFINZI. Do not co-administer other drugs through the same infusion line. |
| **Chemotherapy**†‡ **by Tumor Type2** | |
| Non-squamous | * Cisplatin/pemetrexed§¶ * Carboplatin/pemetrexed§ |
| Squamous | * Carboplatin/paclitaxel * Cisplatin/gemcitabine¶ * Carboplatin/gemcitabine |

\*Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.1

†Refer to the Prescribing Information for dosing information.

‡The platinum-based CT regimen of cisplatin + paclitaxel may be considered; however, this therapy regimen was used outside of the pre-protocol choice.2

§Patients with non-squamous NSCLC only. Administer vitamin B12 and folic acid in line with local practice.2

¶In the event of unfavorable tolerability, patients can switch from cisplatin to carboplatin therapy at any point during the treatment (assuming eligibility for the switched therapy is met). In patients with comorbidities or unable to tolerate cisplatin per providers judgment, carboplatin AUC 5 can be administered from Cycle 1.2

AUC=area under the curve; CT=chemotherapy; USP=United States Pharmacopeia.

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| **Rescue Medications and Flush1,2** | |
| IV flush | Per institution-preferred protocol |
| Infusion-related reactions | Per institution-preferred protocol |
| For immune-mediated adverse reaction management | In general, withhold IMFINZI for severe (**Grade 3)** immune-mediated adverse reactions. Permanently discontinue IMFINZI for life-threatening **(Grade 4)** immune-mediated adverse reactions, recurrent severe **(Grade 3)** immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids.  **Chemotherapy:** Per institution-preferred protocol for Cycles 1-4. |

IV=intravenous.

**Indication:**

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

**IMPORTANT SAFETY INFORMATION**

There are no contraindications for IMFINZI® (durvalumab).

**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 liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. 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 depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI 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 can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. 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.

**Immune-Mediated Colitis**

IMFINZI 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. Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.

**Immune-Mediated Hepatitis**

IMFINZI can cause immune-mediated hepatitis. 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.

**Immune-Mediated Endocrinopathies**

* ***Adrenal Insufficiency***:IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
* ***Hypophysitis***:IMFINZI 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. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
* ***Thyroid Disorders***:IMFINZI 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.
* ***Thyroiditis***: Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
* ***Hyperthyroidism****:* Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
* ***Hypothyroidism***:Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) 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. Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

**Immune-Mediated Nephritis with Renal Dysfunction**

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

**Immune-Mediated Dermatology Reactions**

IMFINZI 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 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) 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 or were reported with the use of other   
PD-1/PD-L1 blocking antibodies.

* ***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, other transplant (including corneal graft) rejection.

**Infusion-Related Reactions**

IMFINZI 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 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. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, 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 its mechanism of action and data from animal studies, IMFINZI 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 advise them to use effective contraception during treatment with IMFINZI and for 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 3 months after the last dose.

**Adverse Reactions**

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

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

**Please see Full Prescribing Information, including Medication Guide for** [**IMFINZI**](https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/9496217c-08b3-432b-ab4f-538d795820bd/9496217c-08b3-432b-ab4f-538d795820bd_viewable_rendition__v.pdf)**.**

**References: 1.** IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2024. **2.** Heymach JV, Harpole D, Mitsudomi T, et al. Perioperative durvalumab for resectable non-small-cell lung cancer. *N Engl J Med*. 2023;389(18):1672-1684 (including supplement and protocol)*.*

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