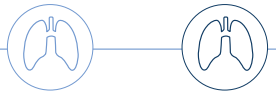
UPDATED EDITION

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

IMMUNE-MEDIATED ADVERSE REACTIONS MANAGEMENT HANDBOOK



Your guide to addressing the immune-mediated adverse reactions (imARs) associated with patients taking PD-L1 blockade therapy

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 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).

Select 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.

PD-L1=programmed death-ligand 1.

Please see additional Select Safety Information on pages 48-51.

Your source for imAR risk management

Dear Healthcare Professional,

There are known serious immune-mediated safety risks associated with IMFINZI® (durvalumab). Through proper knowledge and practice, you can help your patients manage their immune-mediated adverse reactions (imARs).

- Early recognition and treatment of imARs observed with IMFINZI may help keep imARs from becoming more serious[1,2]
- Routine monitoring of patients, including periodic lab tests during and after treatment, is important[1]

IMFINZI®
durvalumab
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- PD-L1–blocking antibody[1]
- Blocks PD-L1 binding to PD-1 and CD80[1]
- Helps overcome and prevent PD-L1–mediated inhibition of T-cell activation[1]

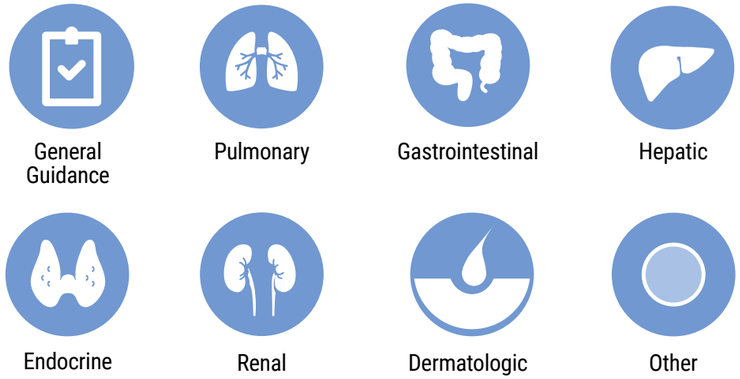
PD-1=programmed cell death protein 1; CD80=cluster of differentiation 80.

How to use this handbook

This handbook was created to inform you about the imARs associated with IMFINZI and the management of these reactions. It is important to recognize and address signs and symptoms early. Management information for imARs included in this handbook:

- Incidence of imARs
- Signs and symptoms to recognize
- Management and dosage modification information
- Follow-up instructions

The sections in this handbook are:



Additional resources included in this handbook:

- Financial assistance details (page 52)
- imAR Quick Reference Guide (in right pocket)

Visit IMFINZIhcp.com for more information

Management of imARs

General Guidance

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

General

General guidance for IMFINZI® (durvalumab) immune-mediated adverse reactions[1]

- IMFINZI is a monoclonal antibody that belongs to a class of drugs that bind to either PD-1 or PD-L1, blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions
- The reactions described in this handbook 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 with a PD-1/PD-L1 blocking antibody. While they usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies

Identification of imARs[1]

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies.

- 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

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions

Please see additional Select Safety Information on pages 48-51.

General

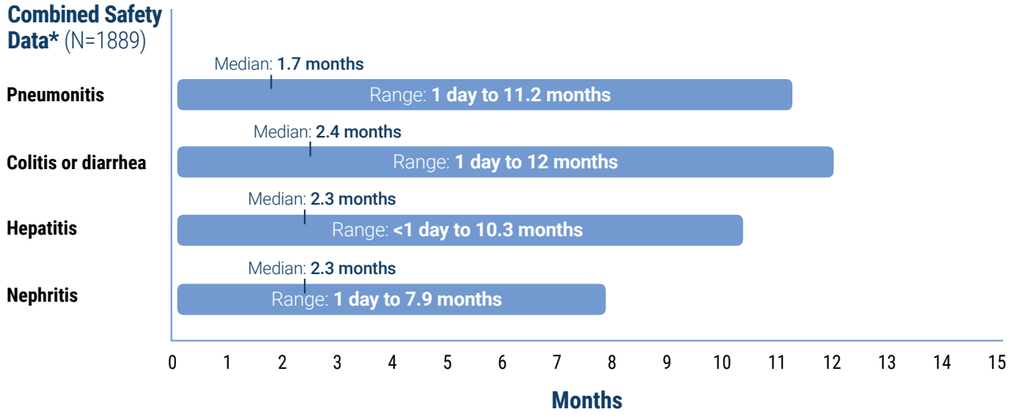
Management strategies[1]

- No dose reduction for IMFINZI is recommended
- In general, withhold IMFINZI for severe (Grade 3) immune-mediated adverse reactions
- 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
- Permanently discontinue IMFINZI for:
  - Life-threatening (Grade 4) immune-mediated adverse reactions
  - Recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment
  - An inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of initiating corticosteroids

These are general guidelines. Please refer to individual sections within this handbook regarding specific imAR management guidelines.

Time to onset of imARs with IMFINZI as a single agent[1-3]

Median time to onset and range reported for select imARs

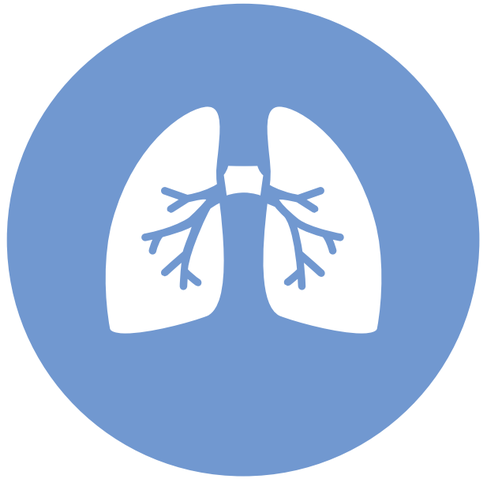


Early recognition and treatment of imARs observed with IMFINZI may help keep imARs from becoming more serious[1,2]

*The combined safety data reflect exposure to IMFINZI in 1889 patients enrolled in the following clinical studies: The PACIFIC study (a randomized, placebo-controlled study that enrolled 475 patients with Stage III non-small cell lung cancer [NSCLC]), Study 1108 (an open-label, single-arm, multicohort study that enrolled 970 patients with advanced solid tumors), and an additional open-label, single-arm trial that enrolled 444 patients with metastatic lung cancer, an indication for which durvalumab is not approved. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more.[1]

Please see additional Select Safety Information on pages 48-51.

Management of imARs



Pulmonary

Pneumonitis

Pulmonary

Immune-mediated pneumonitis with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and additional trials. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

In patients who did not receive recent prior radiation (N=1414)[1]	
All grades	**2.4%**
Grade 3-4	0.4%
Grade 5	<0.1%

In patients who received recent prior radiation (N=709)[1]		
	IMFINZI group (n=475)	Placebo group (n=234)
All grades	**18.3%**	**12.8%**
Grade 3	2.7%	N/A
Grade 5	1.1%	N/A

N/A=not applicable.

- IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation
- Immune-mediated pneumonitis in patients who did not receive recent prior radiation led to permanent discontinuation in 0.4% of the 1414 patients
- Immune-mediated pneumonitis in patients who received IMFINZI who had recent prior radiation led to permanent discontinuation in 6% of the 475 patients
- Systemic corticosteroids were required in 19 of 34 patients with pneumonitis who did not receive chemoradiotherapy prior to initiation of IMFINZI
- Systemic corticosteroids were required in 64 of 87 patients with pneumonitis who had received chemoradiotherapy prior to initiation of IMFINZI, while 2 patients required use of infliximab with high-dose steroids
- The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiotherapy prior to IMFINZI were similar whether IMFINZI was given as a single agent in patients with various cancers in a pooled data set or in patients with ES-SCLC when given in combination with chemotherapy

Please see additional Select Safety Information on pages 48-51.

Pulmonary

Signs and symptoms of pneumonitis[1]

- Cough
- Shortness of breath
- Chest pain

Management strategies for immune-mediated pneumonitis[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[4]*	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	• Symptomatic • Medical intervention indicated • Limiting instrumental ADL†	• Severe symptoms • Limiting self-care ADL‡ • Oxygen indicated	• Life-threatening respiratory compromise • Urgent intervention indicated (eg, tracheotomy or intubation)
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI	Permanently discontinue IMFINZI	
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		

ADL=activities of daily living.
*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]
†Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.[4]
‡Self-care ADL refer to bathing, dressing and undressing, self-feeding, using the toilet, taking medications, and not being bedridden.[4]

Additional withholding information[1]

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if Grade 2 adverse reaction does not recover to ≤Grade 1 or is resolved within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

Gastrointestinal

Colitis

Diarrhea

Gastrointestinal

Immune-mediated colitis with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks, in the PACIFIC study, Study 1108, and additional trials. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated colitis (N=1889)[1]	
All grades	**2%**
Grade 3	0.4%
Grade 4	<0.1%

- IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea
- Immune-mediated colitis led to permanent discontinuation in 0.4% of the 1889 patients
- 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
- Systemic corticosteroids were required in all patients with immune-mediated colitis, while 2 of 37 patients required other immunosuppressants (eg, infliximab, mycophenolate)

Signs and symptoms of colitis[1]

- Diarrhea or more bowel movements than usual
- Stools that are black, tarry, sticky, or have blood or mucus
- Severe abdominal pain or tenderness

Please see additional Select Safety Information on pages 48-51.

Gastrointestinal

Gastrointestinal

Management strategies for immune-mediated colitis[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[4]*	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	• Abdominal pain • Mucus or blood in stool	• Severe abdominal pain • Change in bowel habits • Peritoneal signs	• Life-threatening consequences • Urgent intervention indicated
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI		Permanently discontinue IMFINZI
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		

*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]

Additional withholding information[1]

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if Grade 2 or 3 adverse reaction does not recover to ≤Grade 1 or is resolved within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

Hepatic

Hepatitis

Hepatic

Immune-mediated hepatitis with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and an additional trial. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated hepatitis (N=1889)[1]	
All grades	**2.8%**
Grade 3	1.4%
Grade 4	0.3%
Grade 5	0.2%

- Immune-mediated hepatitis led to discontinuation in 0.3% of the 1889 patients
- Systemic corticosteroids were required in all patients with immune-mediated hepatitis, while 2 of 52 patients required use of mycophenolate with high-dose steroids

Signs and symptoms of hepatitis[1]

- Yellowing of skin or the whites of the eyes
- Severe nausea or vomiting
- Pain on the right side of the abdomen
- Dark urine (tea colored)
- Bleeding or bruising more easily than normal

Please see additional Select Safety Information on pages 48-51.

Hepatic

Management strategies for immune-mediated hepatitis[1]

Hepatitis with no tumor involvement of the liver			
Severity*	—	• ALT or AST increases to >3 and up to 8 × ULN or total bilirubin increases to >1.5 and up to 3 × ULN	• ALT or AST increases to >8 × ULN or total bilirubin increases to >3 × ULN
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI	Permanently discontinue IMFINZI
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month	

Hepatitis with tumor involvement of the liver†			
Severity*	—	• AST or ALT is >1 and up to 3 × ULN at baseline and increases to >5 and up to 10 × ULN **or:** • AST or ALT is >3 and up to 5 × ULN at baseline and increases to >8 and up to 10 × ULN	• ALT or AST increases to >10 × ULN or total bilirubin increases to >3 × ULN
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI	Permanently discontinue IMFINZI
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month	

ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal.
*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.
†If AST and ALT are less than or equal to the ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

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Injection for Intravenous Use 50 mg/mL

Hepatic

Additional withholding information[1]

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if Grade 2 or 3 adverse reaction does not recover to ≤Grade 1 or is resolved within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

Please see additional Select Safety Information on pages 48-51.

Endocrine

- Adrenal insufficiency
- Hypophysitis/hypopituitarism
- Thyroid disorders
- Type 1 diabetes mellitus

Endocrine

Adrenal insufficiency with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and additional trials. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated adrenal insufficiency (N=1889)[1]	
All grades	**0.5%**
Grade 3	<0.1%

- IMFINZI can cause primary or secondary adrenal insufficiency
- Adrenal insufficiency did not lead to permanent discontinuation of IMFINZI in any patients
- Systemic corticosteroids were required in all patients with adrenal insufficiency; of these, the majority remained on systemic corticosteroids

Endocrine

Management strategies for immune-mediated adrenal insufficiency[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[4]*	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	• Moderate symptoms • Medical intervention indicated	• Severe symptoms • Hospitalization indicated	• Life-threatening consequences • Urgent intervention indicated
IMFINZI dosage modifications	Continue treatment with IMFINZI		Withhold IMFINZI until clinically stable or permanently discontinue depending on severity	
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		
Clinical management	—	Initiate symptomatic treatment, including hormone replacement as clinically indicated		

*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]

Endocrine

Immune-mediated hypophysitis/hypopituitarism with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and an additional trial. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated hypophysitis/hypopituitarism (N=1889)	
Grade 3	<0.1%

- 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
- Treatment with systemic corticosteroids was administered in the patient with Grade 3 hypophysitis/hypopituitarism. The event did not lead to permanent discontinuation of IMFINZI

Please see additional Select Safety Information on pages 48-51.

Endocrine

Management strategies for immune-mediated hypophysitis/hypopituitarism[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[4*†]	• Asymptomatic or mild symptoms • Clinical or diagnostic observations only • Intervention not indicated	• Moderate • Minimal, local, or noninvasive intervention indicated • Limiting age-appropriate instrumental ADL‡	• Severe or medically significant, but not immediately life threatening • Hospitalization or prolongation of existing hospitalization indicated • Limiting self-care ADL§	• Life-threatening consequences • Urgent intervention indicated
IMFINZI dosage modifications	Continue treatment with IMFINZI		Withhold IMFINZI until clinically stable or permanently discontinue depending on severity	
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		
Clinical management	Initiate symptomatic treatment, including hormone replacement as clinically indicated			

ADL=activities of daily living.
*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]
†Grade definition for endocrine disorders: other.[4]
‡Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.[4]
§Self-care ADL refer to bathing, dressing and undressing, self-feeding, using the toilet, taking medications, and not being bedridden.[4]

Endocrine

Immune-mediated thyroid disorders with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and an additional trial. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated thyroid disorders (N=1889)[1]	
Thyroiditis	
All grades	**0.5%**
Hyperthyroidism	
All grades	**2.1%**
Hypothyroidism	
All grades	**8.3%**
Grade 3	<0.1%

- IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism
- Systemic corticosteroids were required in 3 of 9 patients with immune-mediated thyroiditis, while 8 patients required endocrine therapy. Permanent discontinuation of IMFINZI resulted from these events in 1 patient
- Systemic corticosteroids were required in 9 of 39 patients with immune-mediated hyperthyroidism, while 35 patients required endocrine therapy
- Systemic corticosteroids were required in 11 of 156 patients with hypothyroidism and 152 of 156 required long-term thyroid hormone replacement

Please see additional Select Safety Information on pages 48-51.

Endocrine

Management strategies for immune-mediated thyroid disorders[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Thyroiditis, hyperthyroidism, and hypothyroidism				
Definition[4*†]	• Asymptomatic • Clinical or diagnostic observations only • Intervention not indicated	• Symptomatic • Limiting instrumental ADL[‡] **Hyperthyroidism:** • Thyroid suppression therapy indicated **Hypothyroidism:** • Thyroid replacement therapy indicated	• Severe symptoms • Limiting self-care ADL[§] • Hospitalization indicated	• Life-threatening consequences • Urgent intervention indicated
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI until clinically stable or permanently discontinue depending on severity		
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		
Clinical management	• Initiate hormone therapy for hypothyroidism or as clinically indicated • Institute medical management of hyperthyroidism as clinically indicated			

ADL=activities of daily living.
*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]
†Grade definition for endocrine disorders: other.[4]
‡Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.[4]
§Self-care ADL refer to bathing, dressing and undressing, self-feeding, using the toilet, taking medications, and not being bedridden.[4]

Endocrine

Type 1 diabetes mellitus[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and an additional trial. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated type 1 diabetes mellitus (N=1889)[1]	
Grade 3	<0.1%

- Type 1 diabetes mellitus can present with diabetic ketoacidosis
- Immune-mediated type 1 diabetes led to permanent discontinuation in <0.1% of the 1889 patients
- The patient with Grade 3 immune-mediated type 1 diabetes mellitus required long-term insulin therapy and IMFINZI was permanently discontinued
- Two additional patients had events of hyperglycemia requiring insulin therapy that did not resolve at time of reporting

Management strategies for type 1 diabetes mellitus[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Definition[4]*	• Abnormal glucose above baseline with no medical intervention	• Change in daily management from baseline for a diabetic • Oral antiglycemic agent initiated • Workup for diabetes	• Insulin therapy initiated • Hospitalization indicated	• Life-threatening consequences • Urgent intervention indicated
IMFINZI dosage modifications	Continue treatment with IMFINZI		Withhold IMFINZI until clinically stable or permanently discontinue depending on severity	
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		
Clinical management	Monitor patients for hyperglycemia or other signs or symptoms of diabetes. Initiate treatment with insulin as clinically indicated			

*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.[4]

Please see additional Select Safety Information on pages 48-51.

Endocrine

Signs and symptoms of endocrinopathies[1]

- Headaches that will not go away or unusual headaches
- Eye sensitivity to light
- Eye problems
- Rapid heartbeat
- Increased sweating
- Extreme tiredness
- Weight gain or weight loss
- Feeling more hungry or thirsty than usual
- Fast and deep breathing
- Sweet smell to your breath
- Sweet or metallic taste in your mouth
- Different odor to your urine or sweat
- Urinating more often than usual
- Hair loss
- Feeling cold
- Constipation
- Your voice gets deeper
- Dizziness or fainting
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Management of imARs

Renal

Nephritis

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Renal

Immune-mediated nephritis with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and additional trials. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated nephritis (N=1889)[1]	
All grades	**0.5%**
Grade 3	<0.1%

- IMFINZI can cause immune-mediated nephritis
- Immune-mediated nephritis led to permanent discontinuation in 0.2% of the 1889 patients
- Systemic corticosteroids were required in all patients with immune-mediated nephritis

Signs and symptoms of nephritis[1]

- Decrease in amount of urine
- Blood in urine
- Swelling in ankles
- Loss of appetite

Please see additional Select Safety Information on pages 48-51.

Renal

Management strategies for immune-mediated renal adverse reactions[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Severity*	—	• Grade 2 or 3 increased blood creatinine		• Grade 4 increased blood creatinine
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI		Permanently discontinue IMFINZI
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		

*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.

Additional withholding information[1]

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if Grade 2 or 3 adverse reaction does not recover to ≤Grade 1 within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

Management of imARs

Dermatologic

Rash or Dermatitis

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Dermatologic

Immune-mediated rash or dermatitis with IMFINZI as a single agent[1]

- The combined safety data (N=1889) reflect exposure to IMFINZI 10 mg/kg every 2 weeks in the PACIFIC study, Study 1108, and additional trials. Among the 1889 patients, 38% were exposed for 6 months or more and 18% were exposed for 12 months or more

Immune-mediated rash or dermatitis (N=1889)[1]	
All grades	**1.8%**
Grade 3	0.4%

- 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 nonexfoliative rashes
- Immune-mediated rash or dermatitis led to permanent discontinuation in 0.1% of the 1889 patients
- Systemic corticosteroids were required in all patients with immune-mediated rash or dermatitis

Signs and symptoms of rash or dermatitis[1]

- Rash
- Itching
- Skin blistering or peeling
- Painful sores or ulcers in mouth, nose, throat or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Please see additional Select Safety Information on pages 48-51.

Dermatologic

Management strategies for exfoliative dermatologic conditions[1]

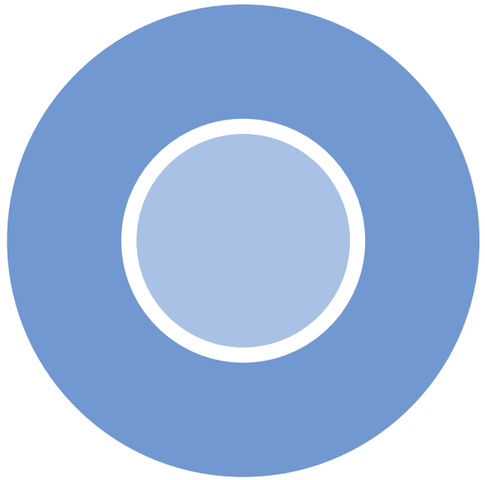
Severity*	—	Suspected SJS, TEN, or DRESS	Confirmed SJS, TEN, or DRESS
IMFINZI dosage modifications	Continue treatment with IMFINZI	Withhold IMFINZI	Permanently discontinue IMFINZI
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month	

SJS=Stevens-Johnson Syndrome; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; TEN=toxic epidermal necrolysis.
*Toxicity grades were defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), v5.

Additional withholding information[1]

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if adverse reaction does not completely or partially resolve (Grade 0-1) within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

Management of imARs



Other

Other imARs

Monitor patients for the following signs and symptoms of other imARs[1]

- Chest pain, irregular heartbeats, shortness of breath or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

Management strategies for myocarditis and neurological toxicities[1]

	Grade 1	Grade 2	Grade 3	Grade 4
Myocarditis				
IMFINZI dosage modifications	May continue treatment with IMFINZI	Permanently discontinue IMFINZI		
Neurological Toxicities				
IMFINZI dosage modifications	May continue treatment with IMFINZI	Withhold IMFINZI	Permanently discontinue IMFINZI	
Steroids	—	In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg-2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month		

Infusion-related reactions

- For Grade 1 or 2, interrupt or slow the rate of infusion
- For Grade 3 or 4, permanently discontinue

Additional withholding information for neurological toxicities[1]:

- Resume in patients with complete or partial resolution (Grade 0-1) after corticosteroid taper
- Permanently discontinue IMFINZI if Grade 2 neurological toxicities do not recover to ≤Grade 1 or are resolved within 12 weeks of corticosteroid initiation
- Permanently discontinue IMFINZI if prednisone (or equivalent) cannot be reduced to less than or equal to 10 mg/day within 12 weeks of corticosteroid initiation

Please see additional Select Safety Information on pages 48-51.

Other imARs

Classwide imARs and imARs with an incidence of <1%[1]:

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

Summary

If your patient is experiencing imARs greater than Grade 1, you may need to withhold or discontinue treatment with IMFINZI. Refer to the table below for guidance.

Dosage reduction of IMFINZI is not recommended.[1]

WITHHOLD IMFINZI*	PERMANENTLY DISCONTINUE IMFINZI*
Specific immune-mediated adverse reactions	**Specific immune-mediated adverse reactions**
Pneumonitis†: Grade 2	**Pneumonitis:** Grade 3 or 4
Colitis†: Grade 2 or 3	**Colitis:** Grade 4
Hepatitis with no tumor involvement of the liver†: ALT or AST >3 and up to 8 × ULN **or** Total bilirubin >1.5 and up to 3 × ULN	**Hepatitis with no tumor involvement of the liver:** ALT or AST >8 × ULN **or** Total bilirubin >3 × ULN
Hepatitis with tumor involvement of the liver†‡: ALT or AST at baseline >1 and up to 3 × ULN and increases to >5 and up to 10 × ULN **or** ALT or AST at baseline >3 and up to 5 × ULN and increases to >8 and up to 10 × ULN	**Hepatitis with tumor involvement of the liver‡:** ALT or AST >10 × ULN **or** Total bilirubin >3 × ULN
Endocrinopathies: Grade 3 or 4, withhold until stable	**Endocrinopathies:** Grade 3 or 4, permanently discontinue depending on severity
Nephritis with renal dysfunction†: Grade 2 or 3 increased blood creatinine	**Nephritis with renal dysfunction:** Grade 4 increased blood creatinine
Exfoliative dermatologic conditions†: Suspected SJS, TEN, or DRESS	**Exfoliative dermatologic conditions:** Confirmed SJS, TEN, or DRESS
Myocarditis: N/A	**Myocarditis:** Grade 2, 3, or 4
Neurological toxicities†: Grade 2	**Neurological toxicities:** Grade 3 or 4
General guidance	**General guidance**
• Grade 3 immune-mediated adverse reactions	• Grade 4 immune-mediated adverse reactions • Recurrent Grade 3 immune-mediated adverse reactions that require systemic immunosuppressive treatment • When withholding IMFINZI, discontinue if no complete or partial resolution (Grade 0 or 1) occurs or if unable to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks of corticosteroid initiation
Other adverse reactions	**Other adverse reactions**
Infusion-related reactions: Grade 1 or 2, interrupt or slow rate of infusion	**Infusion-related reactions:** Grade 3 or 4
RESUME IMFINZI **After complete or partial resolution (Grade 0 or 1) and corticosteroid taper**	

Prescribing Information has additional information for dosage modification and management specific to adverse reactions.

ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis; DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; N/A=not applicable.

*Based on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), version 4.03.

†Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.

‡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.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Select Safety Information (continued)

Immune-Mediated Adverse Reactions (continued)

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 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 when 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.

Select Safety Information (continued)

- ***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), have 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.

Select Safety Information (continued)

<u>Other Immune-Mediated Adverse Reactions</u> (continued)

- ***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 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 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.

Select Safety Information (continued)

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with IMFINZI 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.

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 pneumonitis/radiation pneumonitis (3.4%) and pneumonia (7%)
- 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 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

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

Please see the accompanying complete Prescribing Information, including Medication Guide.

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Financial assistance for your patients

The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for IMFINZI.

Access 360™ provides:

- Assistance with understanding patient insurance coverage and pharmacy options
- Prior authorization support
- Claims and appeal process support

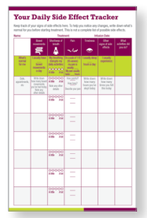
To learn more about the Access 360™ program, please call **1-844-ASK-A360 (1-844-275-2360)**, Monday-Friday, 8 AM-8 PM ET, or visit **MyAccess360.com**.

Additional resources for your patients

Visit **IMFINZIhcp.com** to download these and other materials to support your patients on IMFINZI.

IMFINZI Guide to Monitoring Side Effects

Explains why monitoring is important and what to look for



Daily Side Effect Tracker

A simple tool to help patients track signs of side effects

Immunotherapy Wallet Card

This card is a way for patients to alert ER staff of their current treatment

AstraZeneca offers a range of services for your patients' needs

imAR Quick Reference Guide

- Use the Quick Reference Guide to help monitor your patients' imARs

IMFINZIhcp.com

- Learn more about IMFINZI and download additional resources

IMFINZIhcp.com/nurse-center

- Learn more about IMFINZI and download additional resources for nurses

AstraZeneca Information Center at 800-236-9933

- Call to receive additional information about AstraZeneca products

Nurse Educators

- Connect with a Nurse Educator to receive live patient education and training

Please see the imAR Quick Reference Guide in the pocket to the right to aid in identification of imARs

Contact your IMFINZI Nurse Educator for more information about early identification and intervention of immune-mediated adverse reactions (imARs).

BUSINESS CARD PLACEHOLDER

Contact your IMFINZI Pharmaceutical Sales Specialist for more information about IMFINZI.

BUSINESS CARD PLACEHOLDER

Please see the accompanying complete Prescribing Information, including Medication Guide.

References: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. **2.** Daniels GA, Guerrera AD, Katz D, Viets-Upchurch J. Challenge of immune-mediated adverse reactions in the emergency department. *Emerg Med J.* 2019;36(6):369-377. **3.** Data on file, REF-95603, AstraZeneca Pharmaceuticals. **4.** US Department of Health and Human Services. Common terminology criteria for adverse effects (CTCAE), version 5. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Accessed July 30, 2021.

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IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL