Managing imAEs associated with IMFINZI (durvalumab)

IMFINZI® durvalumab 50 mg/mL concentrate for solution for infusion

This resource is intended for UK healthcare professionals involved in the administration of IMFINZI.

This material focuses on imAEs associated with IMFINZI (durvalumab, an anti–PD-L1 therapy) 50 mg/mL concentrate for solution for IV infusion,[1] which is approved in the UK for treatment of several different solid tumours. Management guidance from ESMO is also provided for each key category of imAE associated with IMFINZI. Please refer to the guidelines for full information and the IMFINZI SmPC for full indications.[1,2]

This material has been funded and created by AstraZeneca. Adverse event reporting and prescribing information can be found on Page 2 (overleaf).

Key: Continue IMFINZI | Consider withholding IMFINZI | Withhold IMFINZI | Discontinue IMFINZI in most cases | Discontinue IMFINZI

imAE categories and events	ESMO Guidelines[2] – Severity and treatment modification			
Pulmonary	**Grade 1**	**Grade 2**	**Grade 3–4**	
Pneumonitis/ILD **Clinical features may include:** non-productive cough, dyspnoea and weight loss[3]	• Consider treatment delay with clinical observation • Monitor symptoms every 2–3 days • If symptoms worsen, treat as Grade 2 or 3–4	• Antibiotics if infection suspected, add oral prednisolone after 48 hrs if no evidence of infection/improvement • Consider pneumocystis prophylaxis if appropriate • If no improvement after 48 hrs of oral prednisolone, treat as Grade 3 • Once improved to baseline, wean oral corticosteroid over 4–6 weeks, titrate to symptoms	• IV methylprednisolone 1–2 mg/kg/day • Empiric antibiotics • Discuss escalation and ventilation • If no improvement/worsening after 48 hrs: – Tocilizumab or infliximab therapy – Consider MMF or cyclophosphamide – Continue IV corticosteroids, wean as indicated • Once improved to baseline, wean oral corticosteroid over ≥6–8 weeks	
Gastrointestinal	**Grade 1**	**Grade 2**	**Grade 3–4**	**Grade 4**
Diarrhoea and enterocolitis **Clinical features may include:** abdominal pain, mucus or blood in stool and increased stool frequency[4]	• Symptomatic management • If failure after 15 days treat as Grade 2	• Symptomatic management • Oral corticosteroids 40–60 mg/day • If failure after 5–7 days, depending on endoscopic severity treat as Grade 3–4	• IV methylprednisolone 1 mg/kg/day • If responsive at Days 3–5, switch to oral prednisolone 1 mg/kg/day	• Immune-mediated colitis or diarrhoea should result in the permanent discontinuation of IMFINZI. Please refer to the IMFINZI SmPC for full information on adverse events and their management[1]
Dermatologic	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Maculopapular rash **Clinical features may include:** skin eruption of flat and raised lesions[5]	• Mild-moderate potency topical corticosteroids • Oral antihistamines • Topical emollient • Avoid sun/ skin irritants	• Moderate-high potency topical corticosteroids • Oral antihistamines if pruritus present • Topical emollient • If refractory, initiate prednisone (0.5–1 mg/kg) or equivalent, tapered over >4 weeks; restart ICI therapy when Grade 1 and prednisone <10 mg/day	• High potency topical corticosteroids • Oral antihistamines if pruritus present • Topical emollient • If refractory, initiate prednisone (0.5–1 mg/kg) or equivalent, tapered over >4 weeks; restart ICI therapy when Grade 1 and prednisone <10 mg/day	• Hospital admission • Rule out systemic complications • IV methylprednisolone 1–2 mg/kg or equivalent tapered over >4 weeks once reaction is controlled • Consider tocilizumab or infliximab if refractory to corticosteroids
Hepatic	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Hepatitis **Clinical features may include:** fatigue, confusion, jaundice, abdominal pain, joint pain/swelling, flu-like symptoms, itching, dark urine, pale stool, rectal bleeding, loss of appetite, ascites and vomiting blood[6]	• Continue ICI therapy	• Avoid hepatotoxic drugs • Corticosteroids 0.5–1.0 mg/kg/day if ALT/AST rising during re-check • If improvement occurs, taper corticosteroids to <10 mg/day and resume ICI therapy • If no improvement, increase dose of corticosteroids 1–2 mg/kg/day and discontinue ICI therapy	• Manage with corticosteroids (dose depends on AST, bilirubin, INR, and albumin levels)	• IV methylprednisolone (2 mg/kg)
Renal	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Renal toxicity/nephritis **Clinical features may include:** dark urine/blood in urine, swelling of the legs/other areas, rashes, joint pain, abdominal pain, high temperature, shortness of breath, jaundice, fatigue and loss of appetite/weight loss[7]	• Repeat creatinine weekly • Withhold nephrotoxic drugs	• Hydration plus regular creatinine and K+ monitoring • Discuss with nephrologist if no improvement, consider biopsy • Corticosteroids if attributable to imAE • Resume ICI therapy if resolved to Grade 1/baseline, or if not attributable to imAE	• Admit to hospital • Repeat creatinine every 24 hrs • Discuss early with nephrologist, consider biopsy • Corticosteroids if worsening • Immune-mediated nephritis should result in the permanent discontinuation of IMFINZI. Please refer to the IMFINZI SmPC for full information on adverse events and their management[1]	• As for Grade 3 • Patient should be managed in-hospital with RRT available
Endocrine	**Hypothyroidism**	**Hyperthyroidism**	**Thyrotoxicosis**	
Thyroid disorders **Clinical features for:** • **Hypothyroidism may include:** chills, fatigue, weakness and hypothyroid heart disease in severe cases[8] • **Hyperthyroidism may include:** heat intolerance, sweating and weight loss and thyroid crisis or thyrotoxic heart disease in severe cases[8]	• Thyroxine 0.5–1.5 µg/kg (start dosing low in elderly or cardiac patients)	• Withhold if patient is unwell with symptoms • Hyperthyroidism often precedes hypothyroidism	• Withhold if patient is unwell with symptoms • Propranolol or atenolol • Carbimazole for Graves' disease • Consider prednisolone for painful thyroiditis and taper	

Please see individual SmPCs for more information before prescribing.

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imAE categories and events	ESMO Guidelines[2] Severity and treatment modification		
Endocrine (continued)	**Grade 1 Vague symptoms**	**Grade 2 Moderate symptoms**	**Grade 3–4 Severe mass effect**
Hypophysitis **Clinical features may include:** fatigue, nausea, vomiting, weakness, headache and loss of libido or erectile dysfunction[9]	• Appropriate hormone replacement therapy. Please refer to the full ESMO guidelines for further advice on hormone replacement therapies • Replace cortisol and/or thyroxine	• Oral prednisolone 0.5–1 mg/kg QD after pituitary axis assessment • If no improvement within 48 hrs, give IV methylprednisolone as for Grade 3–4 • Wean based on symptoms over 1–2 weeks to 5 mg prednisolone (do not stop)	• IV methylprednisolone 1 mg/kg after pituitary axis assessment • Analgesia as needed for headache • Aim to convert to prednisolone and wean as symptoms allow over 2–4 weeks to 5 mg (do not stop)
	Grade 1–2 Fatigue or mood alteration but haemodynamically stable, no electrolyte disturbance		
	• Appropriate hormone replacement therapy • Replace cortisol and/or thyroxine. Please refer to the full ESMO guidelines for further advice on hormone replacement therapies		
Adrenal insufficiency **Clinical features may include:** nausea, loss of appetite, weight loss, fatigue, light-headedness, hypoglycaemia and hypotension[9]	**Grade 1**	**Grade 2[1,2]**	**Grade 3–4**
	• Initiate hydrocortisone 15–20 mg in divided doses if 8 am cortisol <LLN in the absence of a differential diagnosis • If confirmed primary adrenal insufficiency, referral to endocrinologist and education, if unable to take tablets	• Initiate hydrocortisone 30–50 mg total dose regardless of initial cortisol result • Decrease stress dose to maintenance doses after 2–3 days • Ensure an 8 am cortisol is collected before replacement dose is taken	• Inpatient management • IV stress dose hydrocortisone 50–100 mg four times a day or dexamethasone • Rehydration, screen and treat for concurrent sepsis • Review medication for exogenous steroids • Decrease stress dose to maintenance doses after 5–7 days • Resume ICI therapy when clinically stable
		Referral to endocrinologist and medical education	
Diabetes mellitus **Clinical features of diabetes mellitus and diabetic ketoacidosis may include:** fatigue, nausea, vomiting, weight loss and polyuria or polydipsia[2,9]	**Asymptomatic or mild symptoms of hyperglycaemia**	**Hyperglycaemia with moderate symptoms and no ketoacidosis**	**Severe or life-threatening symptoms, ketoacidosis**
	• Monitor glucose at baseline and at each treatment cycle • Insulin replacement as default therapy (initial insulin replacement in new-onset imAE diabetes mellitus: 0.3–0.4 units/kg/day, one half as the long-acting insulin dose and the other half divided into three prandial doses) • In worsening T2DM, dietary measures ± optimisation of oral hypoglycaemic agents	• Monitor glucose at baseline and at each treatment cycle • Insulin replacement as default therapy • In worsening T2DM, dietary measures ± optimisation of oral hypoglycaemic agents • Hydration as clinically appropriate	• Monitor glucose at baseline and at each treatment cycle • Insulin replacement as default therapy • Admit for hospital management • Refer to institutional management guidelines for diabetic ketoacidosis
	Liaise with endocrinologist		

Please see individual SmPCs for more information before prescribing.

Please refer to the following sections of the SmPC for full information on the target indications and safety profile of IMFINZI:[1]

- **Sections 4.1, 4.2, 4.3, 4.5 and 4.6** (indications and safety information for IMFINZI)
- **Section 4.4** (special warnings and precautions for use)
- **Section 4.8** (summary of the safety profile)

Scan or click the QR code to visit the IMFINZI PI:

Scan or click the QR code to visit the ESMO guidelines:

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com or by calling 0800 783 0033.

Abbreviations:
2L, second line; **AE,** adverse event; **ALT,** alanine aminotransferase; **AST,** aspartate aminotransferase; **ESMO,** European Society for Medical Oncology; **hrs,** hours; **ICI,** immune checkpoint inhibitor; **ILD,** interstitial lung disease; **imAE,** immune-mediated adverse event; **INR,** international normalised ratio; **IV,** intravenous; **K,** potassium; **LLN,** lower limit of normal; **MMF,** mycophenolate mofetil; **PD-L1,** programmed death-ligand 1; **PI,** Prescribing Information; **QD,** once daily; **RRT,** renal replacement therapy; **SmPC,** Summary of Product Characteristics; **T2DM,** type 2 diabetes mellitus.

References:
1. IMFINZI (durvalumab) Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed July 2026; **2.** Haanen J, et al. *Ann Oncol*. 2022;33(12):1217–1238; **3.** Zhong L, et al. *Adv Exp Med Biol*. 2020;1244:255–269; **4.** Som A, et al. *World J Clin Cases*. 2019;7(4):405–418; **5.** BMJ Best Practice. Assessment of maculopapular rash. https://bestpractice.bmj.com/topics/en-gb/774. Accessed July 2026; **6.** Johns Hopkins Medicine. Autoimmune hepatitis. Available at: https://www.hopkinsmedicine.org/health/conditions-and-diseases/hepatitis/autoimmune-hepatitis. Accessed July 2026; **7.** NHS. Glomerulonephritis. Available at: https://www.nhs.uk/conditions/glomerulonephritis. Accessed July 2026; **8.** Zhao P, et al. *Front Immunol*. 2025;16:1581057; **9.** Brahmer JR, et al. *J Immunother Cancer*. 2021;9(6):e002435.

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