Genitourinary Masterclass

Best-practice sharing: Practical approaches to patient care – Part 1

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EV as first-line therapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Combination therapy with pembrolizumab.

EV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor, and have received a platinum-containing chemotherapy

EV, enfortumab vedotin.
PADCEV® (enfortumab vedotin). Prescribing Information

PADCEV®
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

astellas

June 2025 | MAT-KR-PAD-2025-00088

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Patient case study: Hyperglycemia

- Male
- **Age: 70** years
- **ECOG PS:** 0
- **GFR:** 50 mL/min

Lifestyle: Active smoker, on diet treatment for type 2 diabetes mellitus

Comorbidities:
- Hypertension
- Type 2 diabetes mellitus

Any other relevant medical history:
- No known drug allergies

Concomitant medications:
- Captopril for hypertension

ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate.

Diagnosis [1/2]

June 2021

Initial presentation

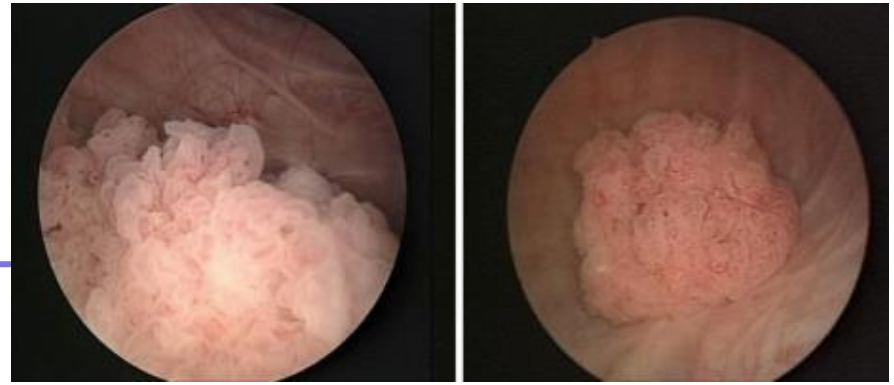
Hematuria

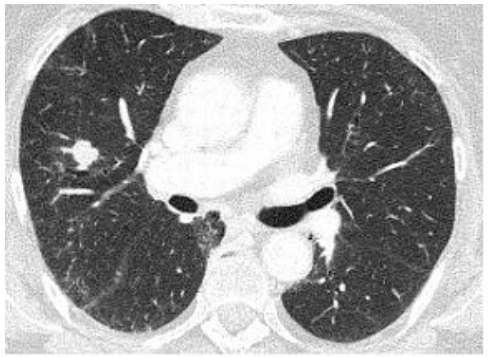
- Ultrasound: Bladder mass
- TURBT: Urothelial carcinoma pT2

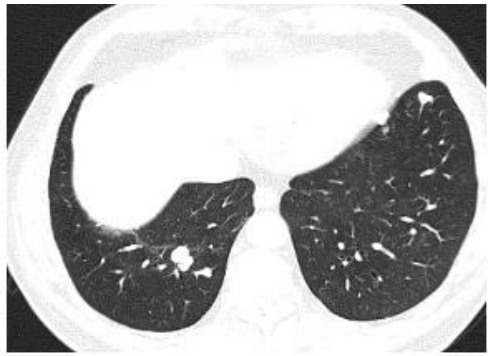
Further investigations

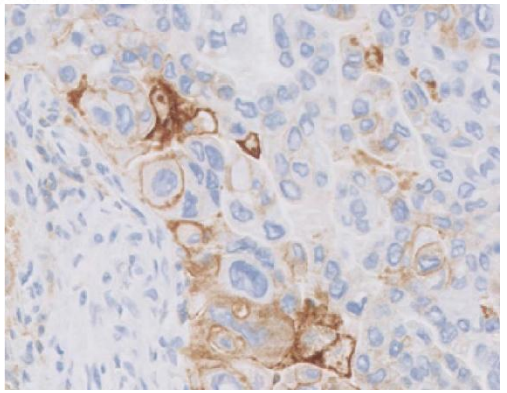
CT scan

- Pulmonary metastasis
- Pelvic lymphadenopathy
- TNM: T2N1M1
- Positive PD-L1 expression with CPS (CPS 20)









Images provided by Dr Rodriguez-Vida with permission.

CPS, combined positive score; CT, computed tomography; p, pathological stage; PD-L1, programmed cell death ligand 1; TNM, tumor, node, metastasis; TURBT, transurethral resection of the bladder.

Diagnosis [2/2]

June 2021

Initial presentation

Hematuria

- Ultrasound: Bladder mass
- TURBT: Urothelial carcinoma pT2

Further investigations

CT scan

- Pulmonary metastasis
- Pelvic lymphadenopathy
- TNM: T2N1M1
- Positive PD-L1 expression with CPS (CPS 20)

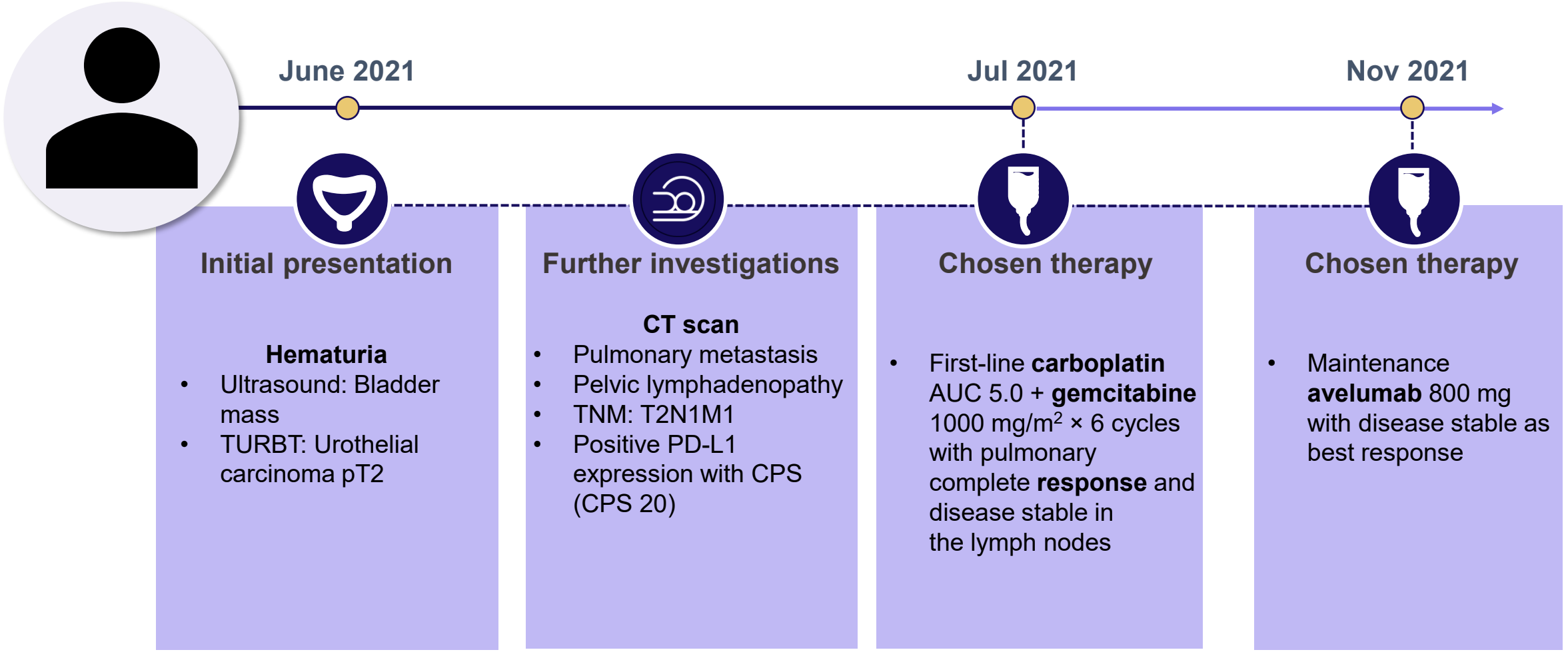
Platinum eligible[1]	
Cisplatin eligible	**Carboplatin eligible**
• ECOG PS 0–1 *and* • GFR >50–60 mL/min *and* • Grade <2 audiometric hearing loss *and* • Grade <2 PN *and* • Cardiac insufficiency NYHA Class <II	• ECOG PS 2 *or* GFR 30–60 mL/min • Or not fulfilling other cisplatin eligibility criteria

Considered **cisplatin ineligible** according to Galsky criteria[1,2] given GFR less than 60 ml/min

CPS, combined positive score; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate; NYHA, New York Heart Association; p, pathological stage; PD-L1, programmed cell death ligand 1; PN, peripheral neuropathy; TNM, tumor, node, metastasis; TURBT, transurethral resection of the bladder.

1. European Association of Urology. EAU guidelines on MIBC and mUC. Available at: https://uroweb.org/guidelines/muscle-invasive-and-metastatic-bladder-cancer. Last accessed: June 2025;
2. Galsky MD et al. *J Clin Oncol* 2011;29:2432–2438.

Treatment initiation, dosage, and schedule



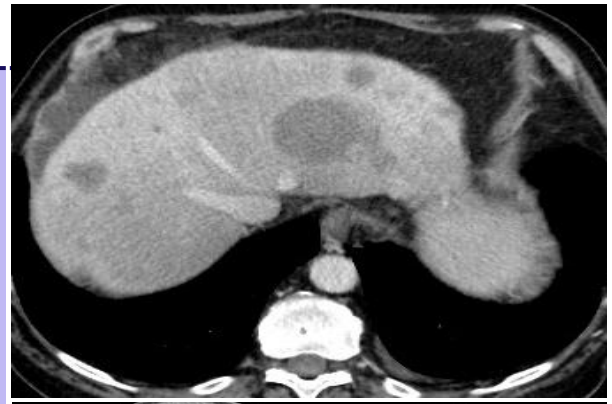
AUC, area under the curve; CPS, combined positive score; CT, computed tomography; p, pathological stage; PD-L1, programmed cell death ligand 1; TNM, tumor, node, metastasis; TURBT, transurethral resection of the bladder.

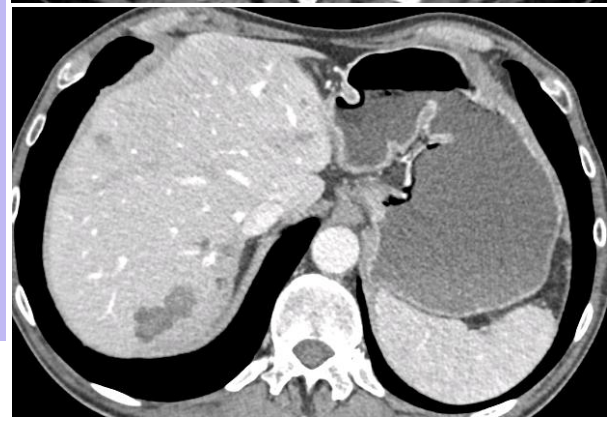
Subsequent treatment [1/2]

June 2022

Progressive disease

- After 7 months of avelumab, the patient presented with disease progression with new liver metastasis





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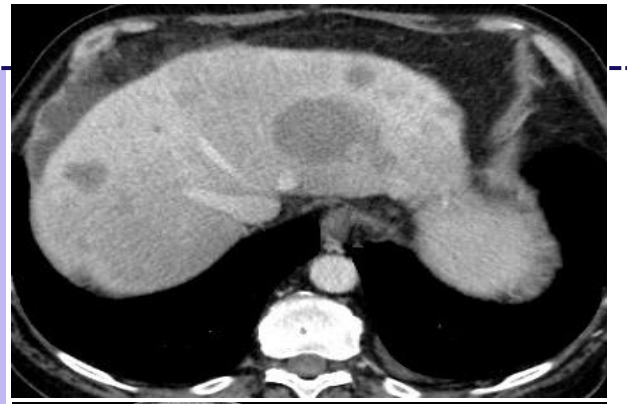
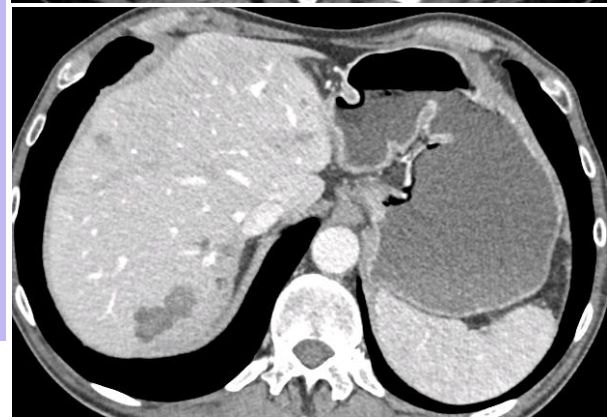
Subsequent treatment [2/2]

June 2022

Progressive disease

- After 7 months of avelumab, the patient presented with disease progression with new liver metastasis





June 2022

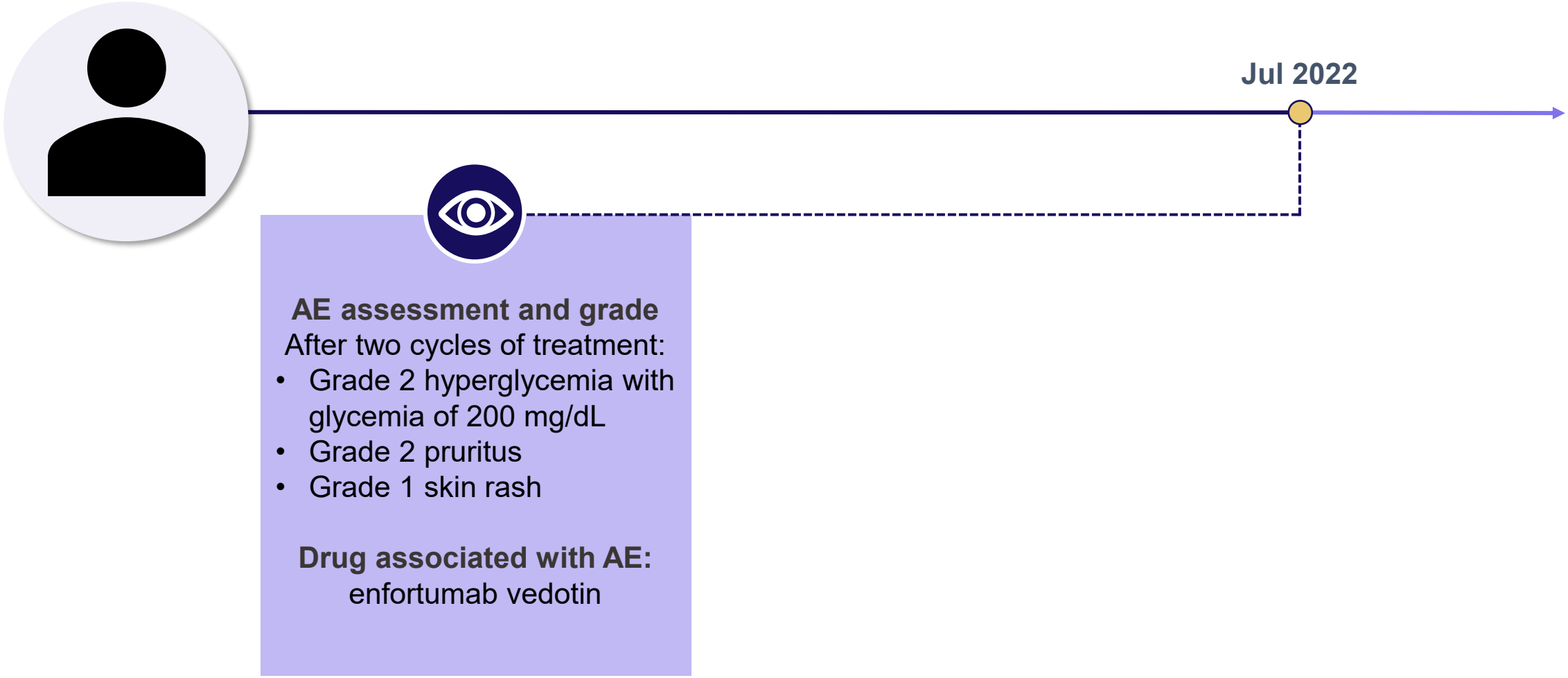
Treatment

- Patient starts treatment with **enfortumab vedotin** at 1.25 mg/kg on Days 1, 8, and 15 every 28 days
- Baseline HbA1c: 7.5%
- Glucose: 145 mg/dL
- BMI: 25 kg/m^2

Images provided by Dr Rodriguez-Vida with permission.

BMI, body mass index; EV, enfortumab vedotin; HbA1c, glycated hemoglobin.

AE presentation and management: Hyperglycemia



AE, adverse event; EV, enfortumab vedotin.

AE presentation and management: Hyperglycemia

Jul 2022

AE assessment and grade

After two cycles of treatment:

- Grade 2 hyperglycemia with glycemia of 200 mg/dL
- Grade 2 pruritus
- Grade 1 skin rash

Drug associated with AE:

enfortumab vedotin

Dosage

- Decided to continue EV at the same dose of 1.25 mg/kg

Management strategies

- Started metformin 500 mg/12 hours, and ebastine (H1 antihistamine) 10 mg/day
- Diet modification and physical exercise were recommended

AE, adverse event; EV, enfortumab vedotin; H1, histamine receptor.

Question for the audience

Which of these statements is true?

- **A** This patient should not have been treated with EV as he has underlying type 2 diabetes mellitus
- **B** Administration of EV should have been discontinued in view of Grade 2 hyperglycemia
- **C** Hyperglycemia with EV is more frequent in patients with a history of hyperglycemia or diabetes mellitus
- **D** In case of Grade 2 hyperglycemia, the dose of EV must be reduced

EV, enfortumab vedotin.

Question for the audience

Which of these statements is true?

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- **B** Administration of EV should have been discontinued in view of Grade 2 hyperglycemia
- **C** Hyperglycemia with EV is more frequent in patients with a history of hyperglycemia or diabetes mellitus[1]
- **D** In case of Grade 2 hyperglycemia, the dose of EV must be reduced

EV, enfortumab vedotin.

1. Powles T et al. *N Engl J Med* 2021;384:1125–1135.

Treatment response

Aug 2022

Response

After three cycles of EV and start of metformin:

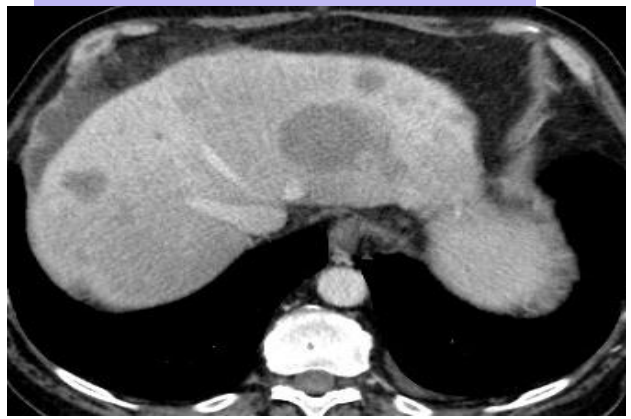
- Glucose blood levels were normalized
- HbA1c: 7.0%
- Disappearance of the rash and improvement of pruritus to Grade 1

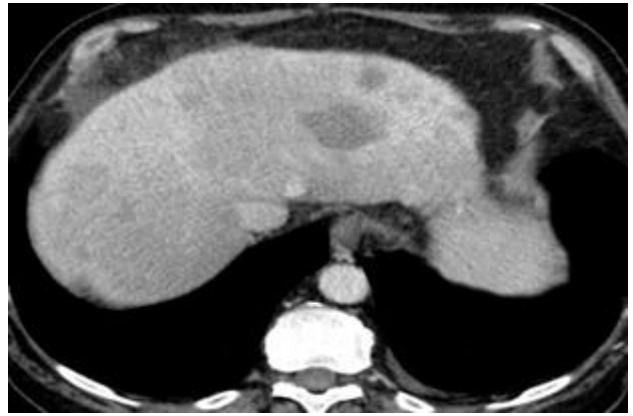
Sep 2022

Response

After four cycles of EV:

- Partial liver response





Images provided by Dr Rodriguez-Vida with permission.

EV, enfortumab vedotin; HbA1c, glycated hemoglobin.

Question for the audience

Which of these statements is true?

- **A** In EV-301, hyperglycemia was amongst the 5 most frequently reported AEs
- **B** The pathophysiological mechanism by which EV causes hyperglycemia is unknown
- **C** Previous insulin treatment contraindicates EV administration because it indicates poorly controlled diabetes
- **D** Hyperglycemia with EV is usually a late cumulative adverse event that appears after many months of treatment

AE, adverse event; EV, enfortumab vedotin.

Question for the audience

Which of these statements is true?

- **A** In EV-301, hyperglycemia was amongst the 5 most frequently reported AEs
- **B** The pathophysiological mechanism by which EV causes hyperglycemia is unknown[1]
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AE, adverse event; EV, enfortumab vedotin.

1. Powles T et al. *N Engl J Med* 2021;384:1125–1135.

EV-related hyperglycemia

SYMPTOMS[1]

- Polydipsia
- Polyuria
- Weight loss
- Asthenia
- Nausea
- Vomiting
- Abdominal pain

DIAGNOSIS[1]

Basal glycemia ≥126 mg/dL
Blood glucose ≥200 mg/dL

ETIOLOGY?

ALWAYS consider the possibility of **Type 2 DM** and **steroid-induced DM** in patients with cancer[3]

Ambulatory management

DIABETIC KETOACIDOSIS[2]

pH + ketone bodies

TREATMENT[1,3]

IV insulin
IV fluid therapy

Admission[1]
+ evaluation by an endocrinologist

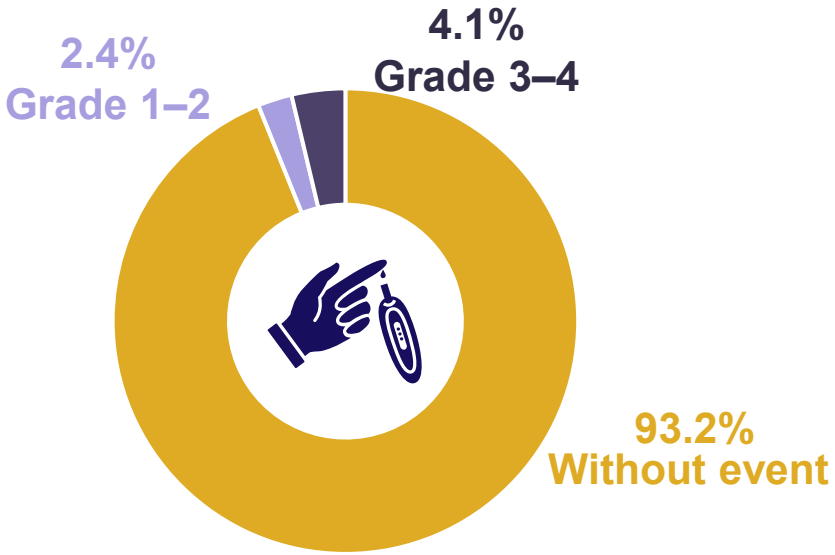
DM, diabetes mellitus; ICI, immune checkpoint inhibitor; IV, intravenous.

1. Stelmachowska-Banaś M, Czajka-Oraniec I. *Endocr Connect* 2020;9:R207–R228; 2. Husebye ES et al. *Eur J Endocrinol* 2022;187:G1–G21; 3. Speaker's own opinion.

Hyperglycemia in EV-301 [1/2]

In EV-301, **18.6%** of patients receiving treatment with EV had **Type 2 DM** or **pre-existing hyperglycemia**[1] and **13.8%** of patients had a **BMI ≥30 kg/m²**[2]

Hyperglycemia in patients receiving treatment with EV in EV-301*[3]



	Enfortumab vedotin (n=296)						Chemotherapy (n=291)					
	Grade						Grade					
	All	1	2	3	4	5	All	1	2	3	4	5
Hyperglycemia[3]* (%)	20 (6.8)	3 (1.0)	4 (1.4)	12 (4.1)	0	1 (0.3)	1 (0.3)	0	1 (0.3)	0	0	0

*Median follow-up of 23.75 months.
BMI, body mass index; DM, diabetes mellitus.
1. Powles T et al. *N Engl J Med* 2021;384:1125–1135; 2. Powles T et al. *N Engl J Med* 2021;384:1125–1135 (supplementary); 3. Rosenberg JE et al. Presented at ASCO 2022. Poster 4516.

Hyperglycemia in EV-301 [2/2]

Hyperglycemia with EV occurred in patients both **with and without pre-existing diabetes mellitus**[1]

Hyperglycemia occurred more **frequently** in patients **with pre-existing hyperglycemia** or a **high BMI (≥30 kg/m²)**[2]

The incidence of Grade 3–4 hyperglycemia consistently **increased in patients with higher BMI** and in patients **with higher baseline HbA1c**[3]

Median time to onset of hyperglycemia for patients receiving treatment with EV: **0.62 months** (range: 0.26–13.7)[4]

Risk factors:[3]

- Previous diabetes mellitus
- Active infection
- Use of systemic corticosteroids

BMI, body mass index; EV, enfortumab vedotin; HbA1c, glycated hemoglobin.

1. Powles T et al. *N Engl J Med* 2021;384:1125–1135 (supplementary); 2. Powles T et al. *N Engl J Med* 2021;384:1125–1135; 3. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9;
4. Rosenberg JE et al. *Ann Oncol* 2023;34:1047–1054.

Hyperglycemia management[1,2]

1) **Assess baseline HbA1c before starting** treatment with EV
2) **Monitor glucose levels** before administration of each dose

- Glucose levels should be **monitored prior to dosing** and **periodically** throughout the course of treatment as clinically indicated in patients with or at risk for diabetes mellitus or hyperglycemia
- Patients with **a history of diabetes or hyperglycemia** should continue to see their endocrinologist or primary care doctor and inform them of their **EV treatment**
- Advise patients to **contact their physician if they experience symptoms** of hyperglycemia (polyuria, polydipsia, blurred vision, confusion, drowsiness, nausea, vomiting, etc.)

EV, enfortumab vedotin; HbA1c, glycated hemoglobin.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9.

Hyperglycemia management

	Grade 1	Grade 2	Grade 3	Grade 4
Dose adjustment	Continue at the same dose[1]	Continue at the same dose[1]	Withhold until elevated blood glucose has improved to ≤13.9 mmol/L (≤250 mg/dL). Resume treatment at the same dose level[1,2]	Suspend EV permanently*[3]
Management strategies	No medical intervention[3]	Start treatment with oral antiglycemic agent[3]	Start treatment with insulin[3]	Urgent intervention required[3]
Patients who develop hyperglycemia should be treated according to standard of care, oral and/or injectable hypoglycemic medication and consider referral to endocrinology[2]				

Glucose levels should be measured prior to dosing and throughout treatment with EV. EV should be temporarily discontinued if levels are >250 mg/dL (13.9 mmol/L) (Grade ≥3)[1]

*Please note that this Is speaker guidance. All HCPs should refer to their own country's specific Prescribing Information.
EV, enfortumab vedotin.
1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9; 3. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025.

Summary

Hyperglycaemia occurred in 6.8% of patients receiving treatment with EV in EV-301;[1] however, proactive management strategies can help to prevent symptoms that might otherwise lead to treatment interruption or discontinuation[2]

Monitoring glucose levels throughout treatment and early intervention including appropriate use of dose modification for Grade ≥3 per SmPC guidance, without impacting the ability to maintain response to EV[1–3]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[5]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilised to manage AEs, to ensure that patients receive optimal treatment outcomes[6]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; PN, peripheral neuropathy; SmPC, Summary of Product Characteristics.

1. Powles T et al. *N Engl J Med* 2021;384:1125–1135; 2. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9; 3. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics;
4. Petrylak D et al. Presented at ASCO 2024. Abstract 4503; 5. Brower B et al. *Front Oncol* 2024;14:1326715.

Genitourinary Masterclass

astellas

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<PADCEV 20mg>

<PADCEV 30mg>

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(7F Parnas tower, 521, Teheran-ro, Gangnam-gu, Seoul, Republic of Korea)

PI, Prescribing Information

Genitourinary Masterclass

Best-practice sharing: Practical approaches to patient care – Part 1

Professor Yüksel Ürün

Ankara University School of Medicine, Ankara

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EV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor and have received a platinum-containing chemotherapy.

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Patient case study: Aged ≥65 years

Mr. Ahmet

- White, Male
- Aged **75** years
- **ECOG PS: 1**
- **GFR: 74** mL/min
- **BMI: 26** kg/m^2
- **HbA1c: 6.2** mmol/L

Lifestyle: Smoking (>40 years)

Employment status/job: Retired teacher

Family history of cancer: None

Comorbidities
- Hypertension
- Asthma

Concomitant medications
- ACE inhibitor
- Inhaled corticosteroids, used as needed

Any other relevant medical history: None

Fictitious patient case study created for illustrative purposes.

ACE, angiotensin-converting enzyme; BMI, body mass index; ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate; HbA1c, glycated hemoglobin.

Treatment initiation, dosage, and schedule

Jun 2019

Initial presentation

Hematuria

TURBT

- Tumor: approximately 4 cm in diameter, extending from posterolateral to the left ureteral orifice toward the left lateral wall of the bladder, with areas showing papillary and solid components
- Biopsy: infiltrative urothelial carcinoma with muscle invasion, T2, high-grade

Chosen therapy

- Four cycles of neoadjuvant GemCis followed by RC

Status

- ypT2N1
- No adjuvant treatment

Fictitious patient case study created for illustrative purposes.

GemCis, gemcitabine + cisplatin; RC, radical cystectomy; TURBT, transurethral removal of bladder tumor; yp, pos-neoadjuvant therapy.

Response to treatment (1/3)

Mar 2024

Presentation

Back pain

CAP CT

- Multiple lesions in both lungs, the right lobe of the liver, retrocrural lymph node, pelvic bones (extending to the iliopsoas muscle and lymph nodes), and the left iliac bone
- All suggestive of widespread metastatic disease

Liver biopsy

- Liver biopsy: UC
- PD-L1 CPS: 25
- HER2-negative
- FGFR3-negative
- MSS

Dosing and schedule

- GemCis with maintenance avelumab administered every 3 weeks, on Days 1 and 8

Fictitious patient case study created for illustrative purposes.

CAP, chest, abdomen, and pelvis; CPS, combined positive score; CT, computed tomography; FGFR3, fibroblast growth factor receptor 3; GemCis, gemcitabine + cisplatin; HER2, human epidermal growth factor receptor 2; MSS, microsatellite stability; PD-L1, programmed cell death ligand 1; UC, urothelial carcinoma.

Response to treatment (2/3)

Oct 2024

Disease progression

- Patient progressed after GemCis × 6 with maintenance avelumab

PET-CT

- Multiple hypermetabolic lesions in both lungs and the right lobe of the liver, retrocrural lymph node, pelvic bones (extending to the iliopsoas muscle and lymph nodes), left iliac bone, and a suspicious focus in the left kidney cortex
- All suggestive of widespread metastatic disease

Chosen therapy

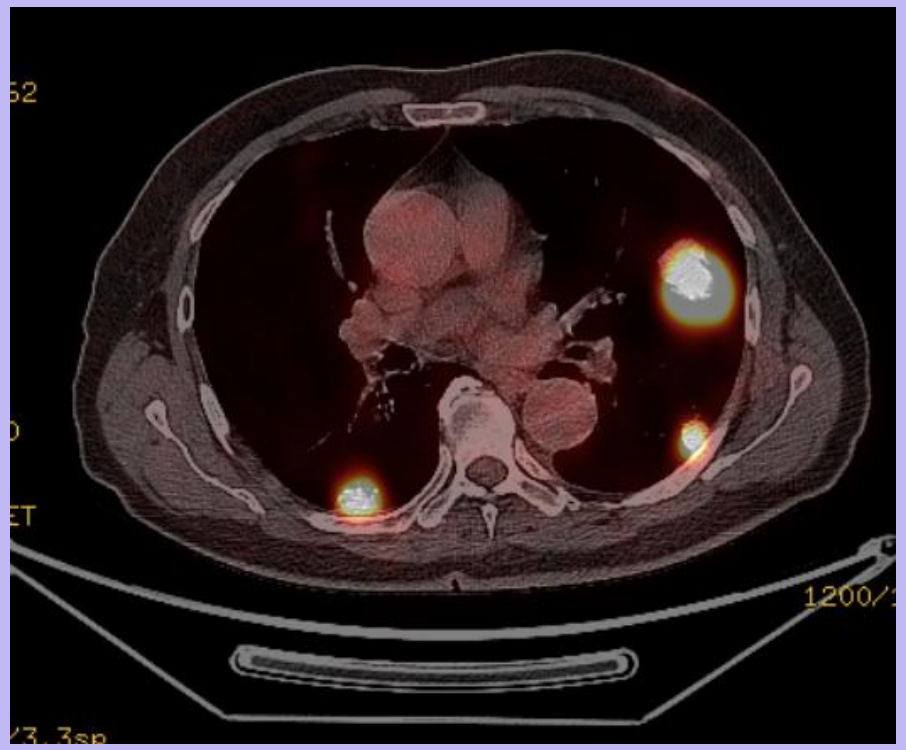
- EV 1.25 mg/kg on Days 1, 8, and 15 of each 28-day cycle

Fictitious patient case study created for illustrative purposes.

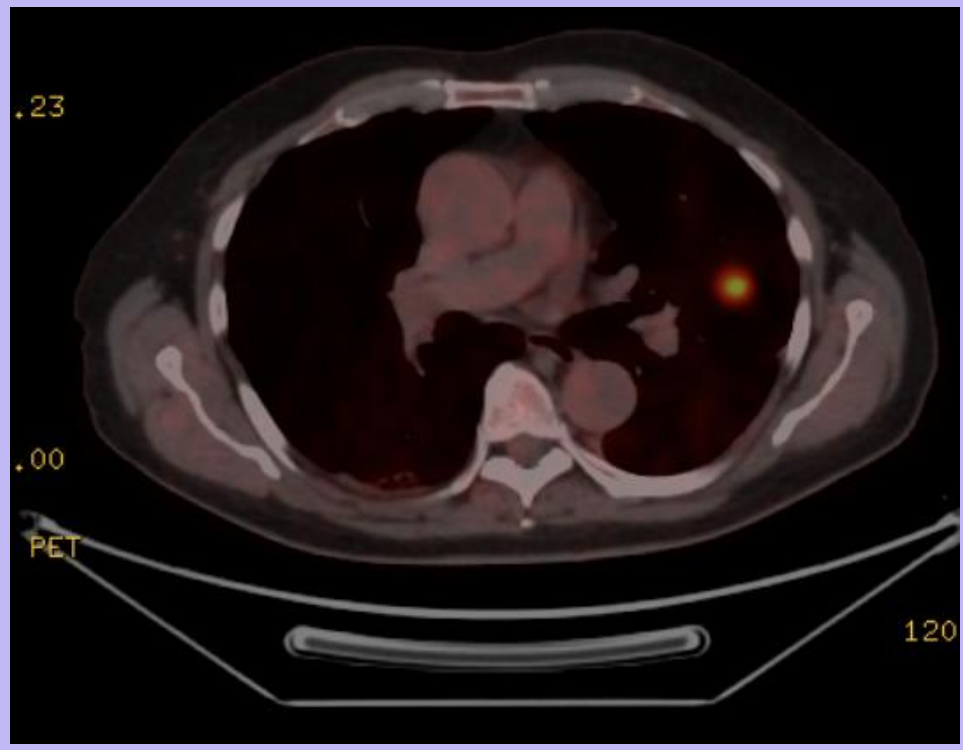
CT, computed tomography; EV, enfortumab vedotin; GemCis, gemcitabine + cisplatin; PET, positron emission tomography.

Response to treatment (3/3)

EV – three cycles



Oct 2024



Jan 2025

Fictitious patient case study created for illustrative purposes. Images provided by Prof. Ürün with permission.

EV, enfortumab vedotin.

AE presentation and management

Feb 2025

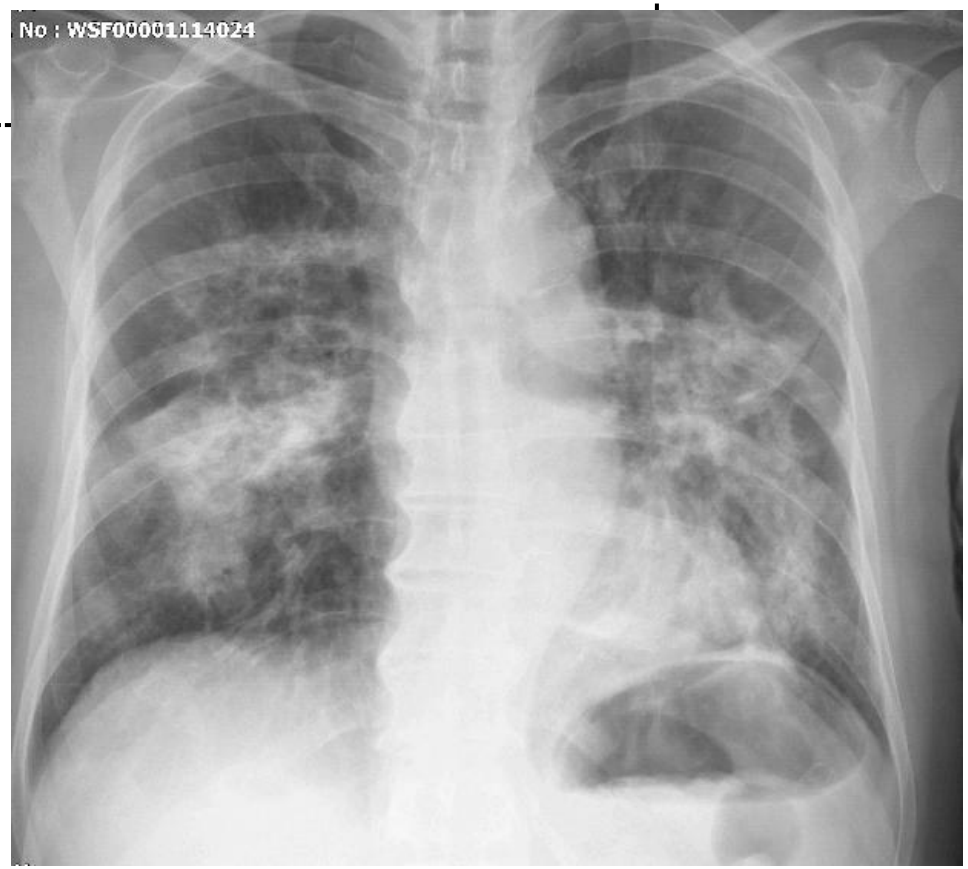
AE symptoms

- Dyspnea
- No fever
- No cough

AE assessment and grade

- WBC: 7500/mm^3
- CRP: 22 mg/dL
- Negative COVID-19 PCR

EV associated with Grade 2 lung toxicity



Fictitious patient case study created for illustrative purposes.

AE, adverse event; CRP, C-reactive protein; EV, enfortumab vedotin; PCR, polymerase chain reaction; WBC, white blood cell.

Question for the audience

How would you approach managing this adverse event?

- **A** Continue EV at the current dose
- **B** Withold EV until Grade ≤1
- **C** Permanently discontinue EV
- **D** Other

EV, enfortumab vedotin.

Question for the audience

How would you approach managing this adverse event?

- **A** Continue EV at the current dose
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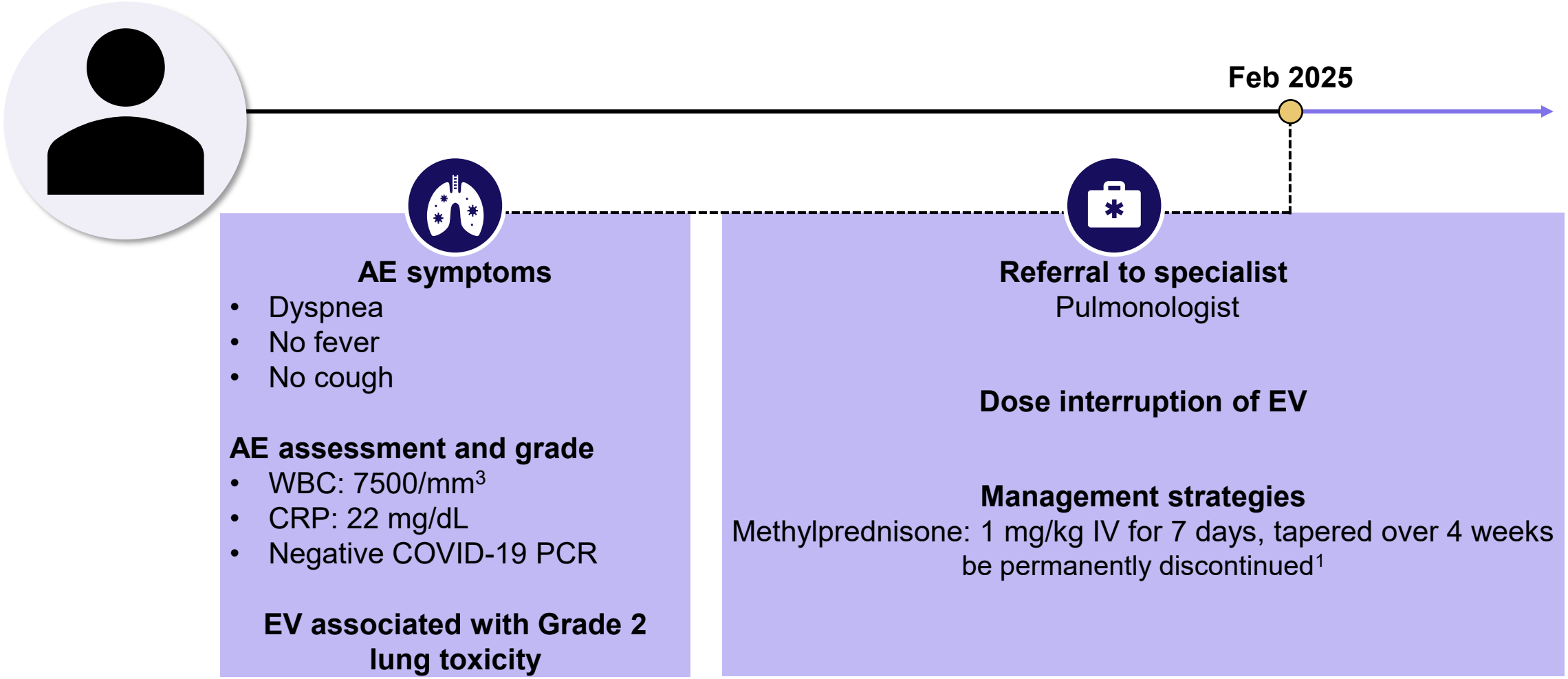
- **D** Other

EV, enfortumab vedotin.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

AE presentation and management

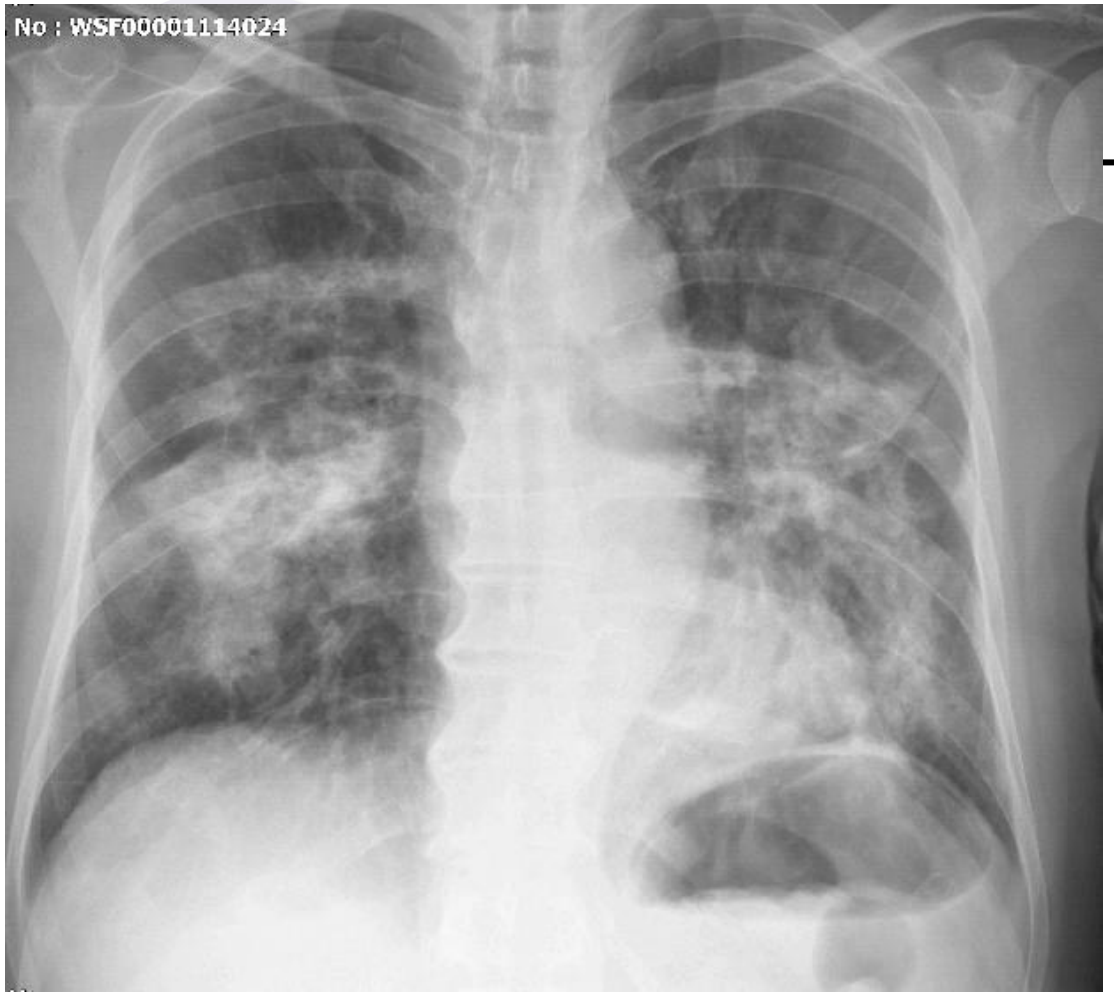


Fictitious patient case study created for illustrative purposes.

AE, adverse event; CRP, C-reactive protein; EV, enfortumab vedotin; ILD, interstitial lung disease; IV, intravenous; PCR, polymerase chain reaction; SmPC, Summary of Product Characteristics; WBC, white blood cell.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

AE management



Mar 2025

Effect of AE management strategies on AEs

- Recovered very well

May 2025

Subsequent treatment

- EV 1 mg/kg on Days 1 and 8 of each 21-day cycle

Fictitious patient case study created for illustrative purposes. Images provided by Prof. Ürün with permission.

AE, adverse event; EV, enfortumab vedotin.

SmPC management guidance

AESI	Severity	Dose modification
Pneumonitis/ ILD	**Grade ≥3**	Permanently discontinue
	Grade 2	Withhold until Grade 1, then resume at the same dose level or consider dose reduction by one dose level

Dose reduction schedule

Starting dose
1.25 mg/kg*
up to 125 mg

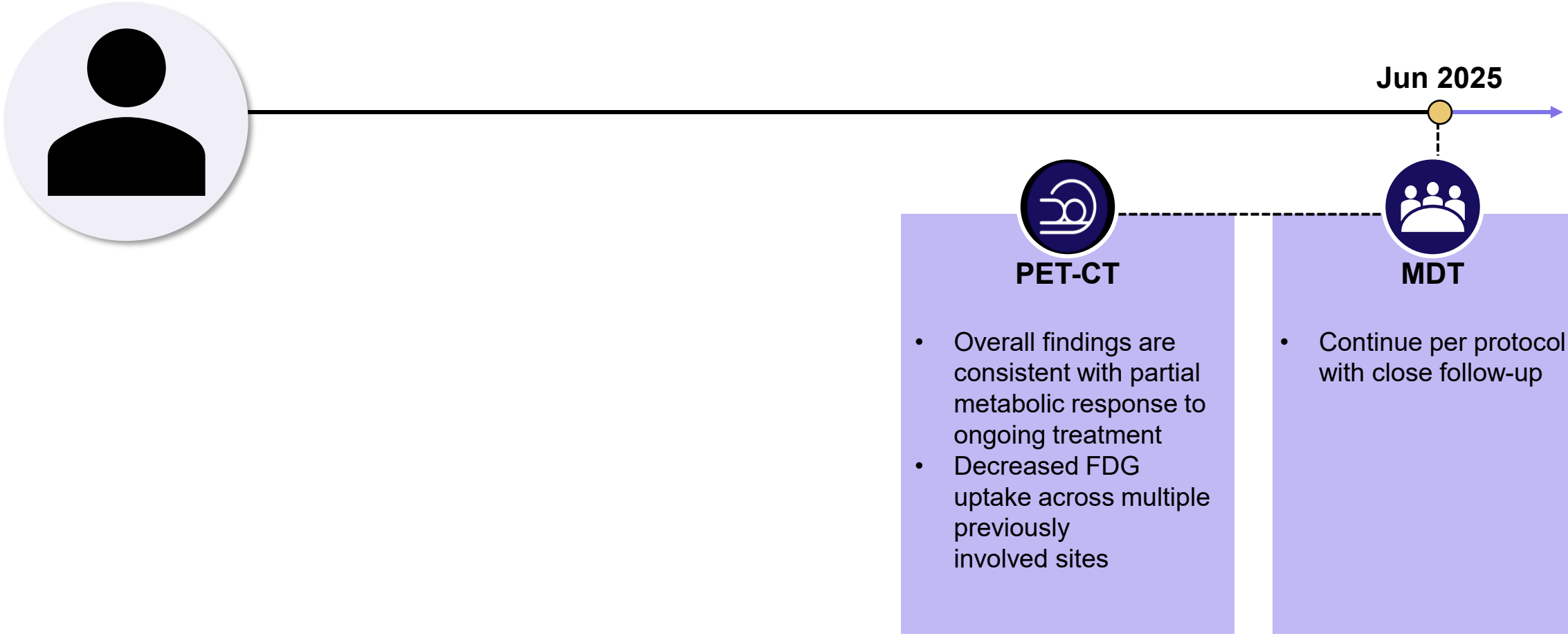
First dose reduction
1.00 mg/kg
up to 100 mg

Second dose reduction
0.75 mg/kg
up to 75 mg

Third dose reduction
0.50 mg/kg
up to 50 mg

*Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0 (NCI-CTCAE v5.0) where Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe and Grade 4 is life-threatening.
AESI, adverse event of special interest; EV, enfortumab vedotin; SJS, Stevens–Johnson syndrome; SmPC, Summary of Product Characteristics; TEN, toxic epidermal necrolysis.
PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

Long-term response to treatment



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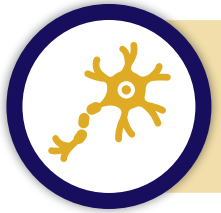
CT, computed tomography; FDG, fluorodeoxyglucose; MDT, multidisciplinary team; PET, positron emission tomography.

Summary



In clinical studies of EV as monotherapy, pneumonitis/ILD occurred in 3.3% of patients receiving treatment with EV, with less than 1% experiencing events of Grade 3 or 4. Proactive management strategies can help to ensure that patients continue to maximize clinical benefits with EV[1]

Prompt intervention with the use of dose modifications provides the best chance for resolution of pulmonary toxicities, without impacting the ability to maintain response to EV[1]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[2]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilized to manage AEs, to ensure that patients receive optimal treatment outcomes[1]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; ILD, interstitial lung disease; PN, peripheral neuropathy.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Brower B et al. *Front Oncol* 2024;14:1326715.

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Genitourinary Masterclass

Best-practice sharing: Practical approaches to patient care – Part 1

Dr Phichai Chansriwong

Medical Oncologist, Ramathibodi Hospital, Bangkok, Thailand

EV as first-line therapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Combination therapy with pembrolizumab.

EV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor, and have received a platinum-containing chemotherapy

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June 2025 | MAT-KR-PAD-2025-00070

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- Travel Expense: Ipsen, Merck Sereno

Patient case study: Non-response to prior PD-1/L1 inhibitor

Mr SN

- White, male
- **Age: 70** years
- **ECOG PS: 1**
- **GFR: 50** ml/min
- **BMI: 27** kg/m^2
- **HbA1c:** 7.0%

Lifestyle: Active

Employment status: Business owner

Family history of cancer: No

Comorbidities:

- Diabetes mellitus
- Hypertension
- Dyslipidaemia

Any other relevant medical history:

- History of prostate cancer s/p RP with RT 2008
- RCC s/p left partial nephrectomy in 2015

Concomitant medications:

- Metformin 500 mg BID (one tablet)
- Enalapril 5 mg BID (one tablet)
- Flavoxate 200 mg TID (one tablet)

Fictitious patient case study created for illustrative purposes.

BID, twice daily; BMI, body mass index; ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate; HbA1c, glycated haemoglobin; PD-1, programmed cell death protein 1; PD-L1, programmed cell death ligand 1; RCC, renal cell carcinoma; RP, radical prostatectomy; RT, radiotherapy; s/p, status post; TID, three times daily.

Treatment initiation, dosage, and schedule

Jun 2023

Initial presentation

Gross haematuria

- Cystoscopy found mass at lateral wall of bladder
- TURBT: Infiltrative TCC, high grade with squamous differentiation, invasion of muscularis propria, no LVI
- IHC: CK6/6 and CK14 positive, GATA3, p63 and uroplakin positive, PSA negative

Further investigations

CT scan

- Diffuse irregular thickened wall including bilateral UVJs
- Mild right hydronephrosis
- Partial nephrectomy left with left PCN
- No lung and liver lesions

Jun–Aug 2023

Chosen therapy

- Neoadjuvant
- Cisplatin + gemcitabine on D1, D8 ×3 cycles
- CT scans: **New 1.2 cm lung nodule LUL and several tiny lung nodules**

Sep–Nov 2023

Dosing and schedule

- FDG PET-CT scans showed bladder mass SUV 55.1 and LUL lesion SUV 7.58
- PD response on neoadjuvant cisplatin + gemcitabine
- Test PD-L1 22C3 CPS 15, FGFR no alteration
- 1L pembrolizumab 200 mg Q3W ×4 cycles

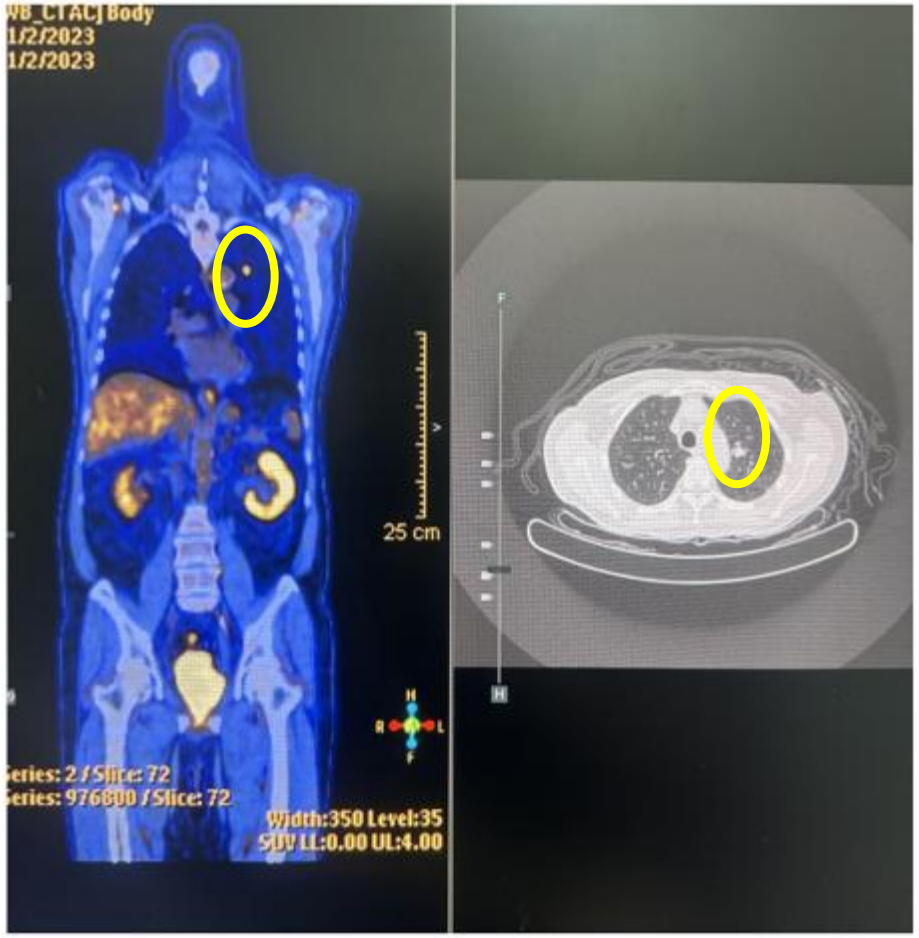
Fictitious patient case study created for illustrative purposes.

1L, first-line; CK, cytokeratin; CPS, combined positive score; CT, computed tomography; D, Day; FDG, fluorodeoxyglucose; FGFR, fibroblast growth factor receptor; IHC, immunohistochemistry; LUL, left upper lobe; LVI, lymphovascular invasion; PCN, percutaneous nephrostomy; PD, progressive disease; PD-L1, programmed cell death ligand 1; PET, positron emission tomography; PSA, prostate-specific antigen; Q3W, every 3 weeks; SUV, standardised uptake value; TCC, transitional cell carcinoma; TURBT, transurethral removal of bladder tumour; UVJ, uterovesical junction.

Initial patient response to treatment

- **CT scans after four cycles of pembrolizumab:**
  New lymphadenopathy at bilateral external iliac, left internal iliac and presacral regions, likely node metastasis
- **FDG PET-CT scans on 2 Nov 2023:**
  Bladder mass involving left side and anterior aspect of the bladder and left UVJ,
  left hydronephrosis
  - Five FDG-avid lymph nodes,
    1.1 cm LUL lesions

2 Nov 2023



Fictitious patient case study created for illustrative purposes.
Images used with Dr Phichai's permission.
CT, computed tomography; FDG, fluorodeoxyglucose; LL, lower limit; LUL, left upper lobe; PET, positron emission tomography; SUV, standardized uptake value; UL, upper limit; UVJ, uterovesical junction; WB-CTAC, whole body CT-based attenuation correction.

Question for the audience

What treatment approach would you favour for this patient?

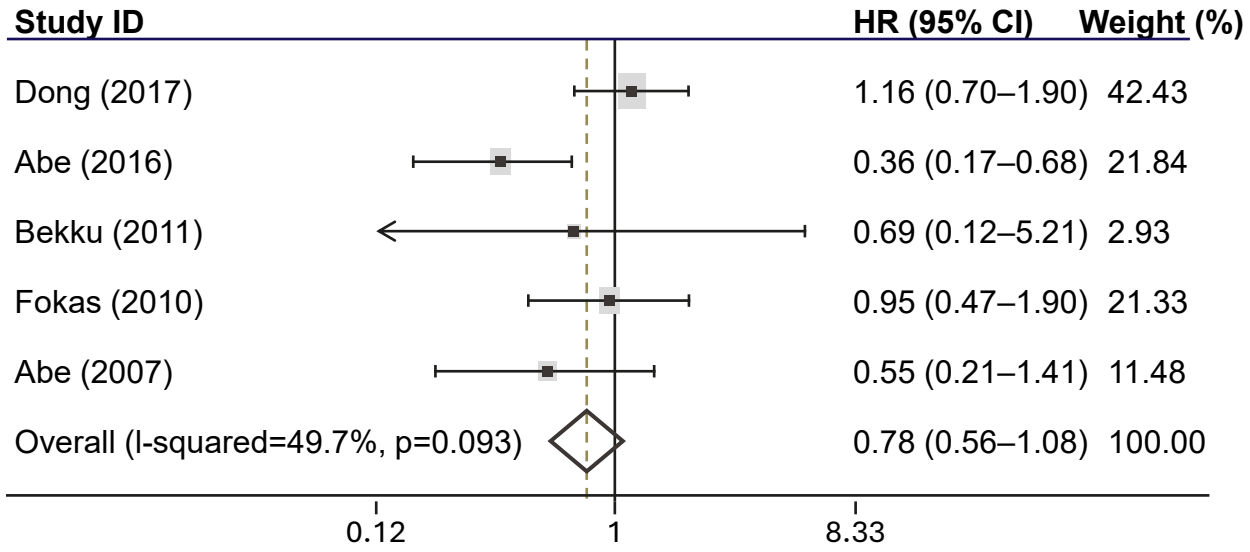
- **A** EV monotherapy
- **B** Single-agent chemotherapy
- **C** Metastasectomy
- **D** Other

EV, enfortumab vedotin.

There is no strong evidence to support the role of metastasectomy

- There is no strong evidence to support the role of metastasectomy in improving survival in patients with mUC[1–3]
  - Findings from a single-centre study suggest that metastasectomy **may not be suitable** for all patients such as those with **hepatic metastases** or **primary UTUC** involvement[1]
  - As there is a large degree of **variability in reporting elements** and multiple sources of bias due to the **lack of prospective randomised trials**, limited conclusions can be drawn[2]
  - In a network meta-analysis, metastasectomy was **not associated with a benefit in OS**[3]

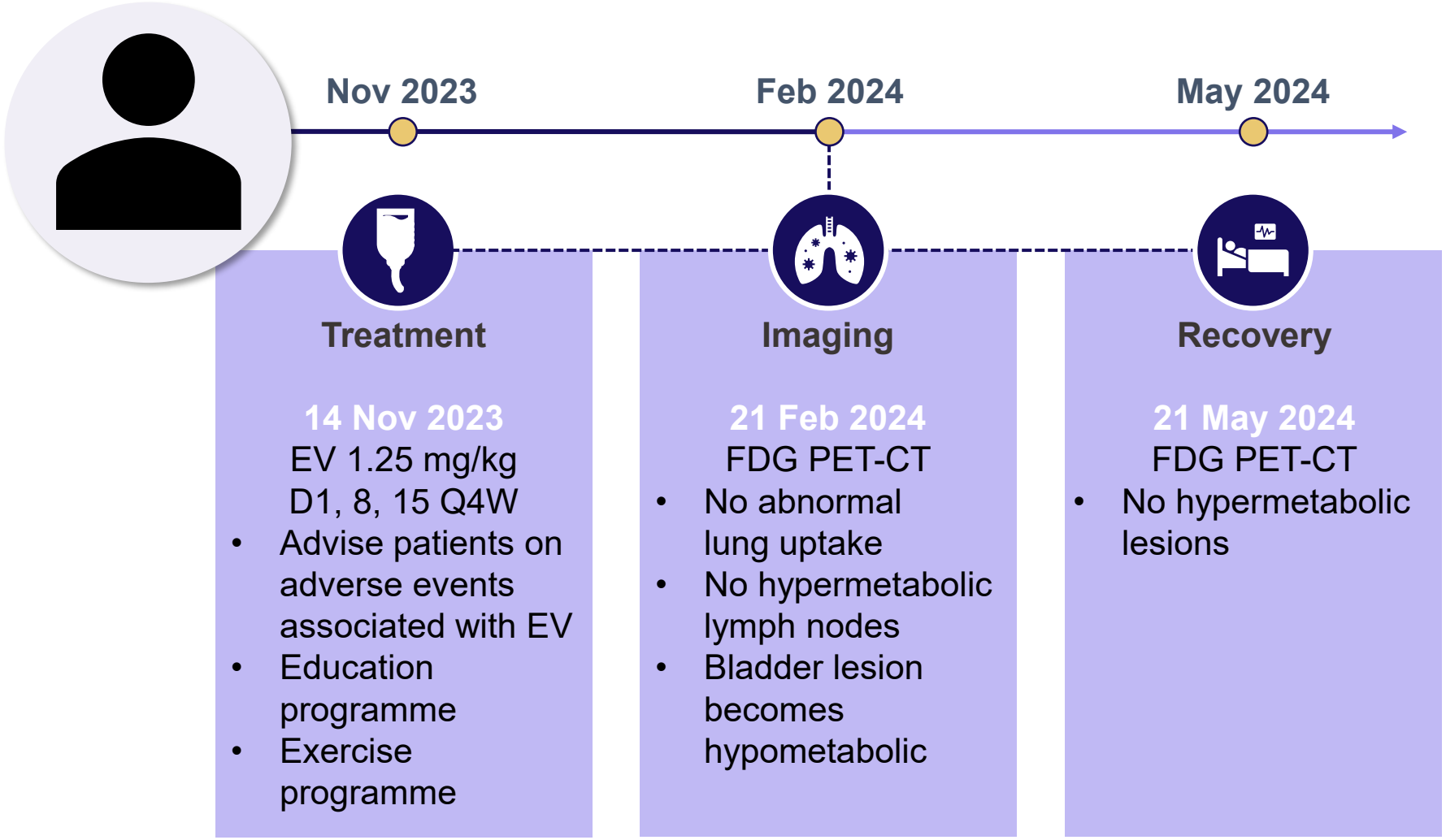
OS: Metastasectomy vs. non-surgical[3]



CI, confidence interval; HR, hazard ratio; mUC, metastatic urothelial carcinoma; OS, overall survival; UTUC, upper tract urothelial carcinoma.

1. Muilwijk T, et al. *Transl Androl Urol* 2020;9:1296–1305; 2. Patel V, et al. *Bladder Cancer* 2017;3:121–132; 3. Xing Q, et al. *Transl Cancer Res* 2020;9:1567–1576.

Patient response to treatment [1/4]



Fictitious patient case study created for illustrative purposes.

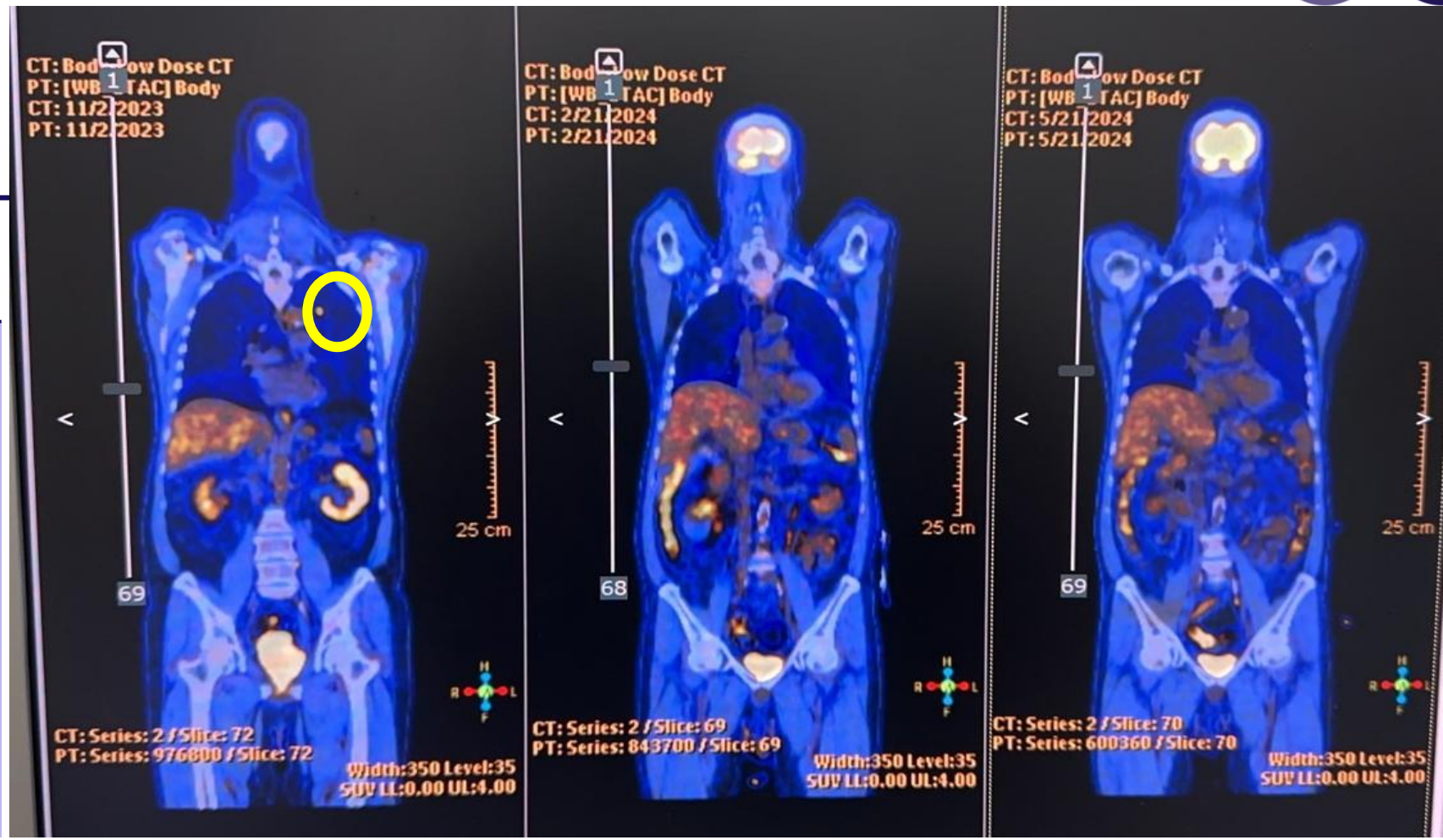
CT, computed tomography; D, Day; EV, enfortumab vedotin; FDG, fluorodeoxyglucose; PET, positron emission tomography; Q4W, every 4 weeks.

Patient response to treatment [2/4]

Nov 2023

Treatment

14 Nov 2023
EV 1.25 mg/kg
D1, 8, 15 Q4W



PET-CT
2 Nov 2023

PET-CT
21 Feb 2024

PET-CT
21 May 2024

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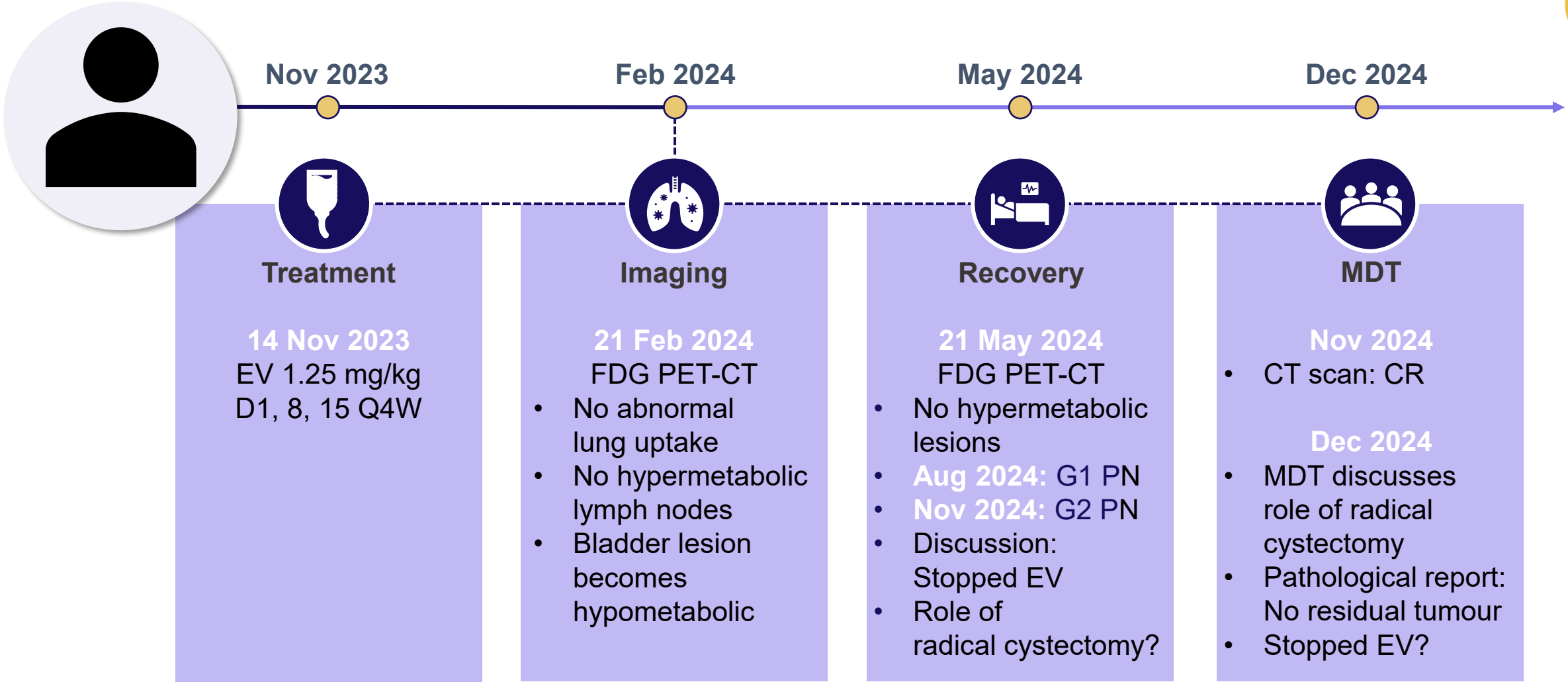
CT, computed tomography; D, Day; EV, enfortumab vedotin; LL, lower limit; PET, positron emission tomography; SUV, standardized uptake value; UL, upper limit; Q4W, every 4 weeks; WB-CTAC, whole body CT-based attenuation correction.

Patient response to treatment [3/4]



Fictitious patient case study created for illustrative purposes.

CR, complete response; CT, computed tomography; D, Day; EV, enfortumab vedotin; FDG, fluorodeoxyglucose; G, Grade; MDT, multidisciplinary team; PET, positron emission tomography; PN, peripheral neuropathy; Q4W, every 4 weeks.

Patient response to treatment [4/4]

Dec 2024: Pathological diagnosis

1. Urinary bladder, robotic cystectomy:
   - No residual tumour detected
   - Presence of subepithelial granulation tissues, focal submucosal and muscularis propria fibrosis
   - All margins are negative for carcinoma
2. Distal ureter, right, excision:
   - No malignancy
3. Distal ureter, right, excision:
   - No malignancy
4. Urinary bladder mucosa, biopsy:
   - Chronic inflammation with granulation tissue
   - No malignancy

Fictitious patient case study created for illustrative purposes.

AE presentation and management

AE symptoms

- C1D15: Skin rash Grade 1
- C2D1: Grade 3 hyperglycaemia (BS 280 mg/dL)
- C2D8, C3D8: Recurrent UTI
  C8D1: Grade 1 neuropathy
- C9D1: Grade 2 neuropathy (slightly limits IADLs)
- C12D15: Grade 2 neuropathy (moderately limits IADLs)

Drug associated with AE: EV

Referral to specialist:

- C2D1: Grade 3 hyperglycaemia: Consult endocrine specialist

Management strategies:

- **Skin rash** Grade 1: TA lotion
- Hyperglycaemia: Adjust gemigliptin one tablet once daily; insulin BS 155 mg/dL (Grade 1)
- C9D1: Neuropathy; adjust EV to 1 mg/kg
- C12D1: Stop EV

Fictitious patient case study created for illustrative purposes.

AE, adverse event; BS, blood sugar; C, Cycle; D, Day; EV, enfortumab vedotin; IADLs, Instrumental Activities of Daily Living; TA, triamcinolone acetonide; UTI, urinary tract infection.

Peripheral neuropathy is a common AE associated with EV

Incidence of PN associated with EV

Across clinical studies of 793 patients receiving EV, peripheral neuropathy occurred in 53% of patients

- 5% of patients experienced severe peripheral neuropathy (Grade 3 or 4)
- Median time to onset of Grade ≥2 peripheral neuropathy was 5 months

Peripheral neuropathy is a common AE associated with EV

Guidance for PN

Grade 2

- Withhold until Grade ≤1
- For first occurrence, resume treatment at the same dose level
- For a recurrence, withhold until Grade ≤1, then resume treatment reduced by one dose level

Grade 3

- Permanently discontinue

AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy.
PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

The effect of exercise on PN

A review in 2004 found inadequate evidence from randomised controlled trials to evaluate the effect of exercise on disability in peripheral neuropathy[1,2]

There was evidence that strengthening exercises moderately improve muscle strength in people with peripheral neuropathy[1,2]

The impact of exercise on CIPN was discussed at the MASCC annual meeting in 2022 highlighting three types of intervention[2,3]

- Exercise started before administration of chemotherapy and continued – **most effective**
- Exercise only before chemotherapy – **partial neuroprotection**
- Exercise after chemotherapy – **partial therapeutic effect**

CIPN, chemotherapy-induced peripheral neuropathy; MASCC, Multinational Association for Supportive Care in Cancer; PN, peripheral neuropathy.

1. White CM et al. *Cochrane Database Syst Rev* 2004;(4):CD003904; 2. Speaker's own opinion; 3. Slivicki RA et al. *Neurobiol Pain* 2019;6:100035.

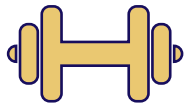
Exercise and patient care for CIPN

Prevention

Endurance and/or resistance training
- May improve sensory symptoms, prevent strength loss, improve balance, reduce falls and fall-related injury and stabilise the functional capacity of patients

Balance training
- Beneficial effects on balance, pain, muscle strength and fitness

Whole body vibration training



Rehabilitation

Endurance and/or resistance training
- May improve CIPN symptoms, functional tests and pain

Balance training
- May improve balance function, postural control, QOL and reduce symptom severity

Whole body vibration training
- May improve CIPN symptoms and muscular power

CIPN, chemotherapy-induced peripheral neuropathy.
Stubblefield MD et al. *Cancer* 2012;118:2250–2260.

Long-term response to treatment

May 2025

Imaging

5 Sep 2024

- FDG PET-CT: CR response

27 Mar 2025

- CT scans: CR response

MDT

- Endocrine:
  - HbA1c: 6.64%
  - Metformin and gemigliptin
  - Stop insulin
- Neuropathy improved to Grade 1
- **No further EV treatment**

Fictitious patient case study created for illustrative purposes.

CR, complete response; CT, computed tomography; EV, enfortumab vedotin; FDG, fluorodeoxyglucose; HbA1c, glycated haemoglobin; MDT, multidisciplinary team; PET, positron emission tomography.

Summary

PN is a frequent, dose-limiting toxicity associated with EV use; however, proactive management strategies can help to ensure that patients continue to maximise clinical benefits with EV[1]

Early recognition of treatment-emergent PN and prompt intervention with the use of dose modifications provides the best chance for resolution, without impacting the ability to maintain response to EV. There are no medications specifically recommended for managing EV-induced PN, favouring non-pharmacological interventions[1–3]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[4]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilised to manage AEs, to ensure that patients receive optimal treatment outcomes[1]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; PN, peripheral neuropathy.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Speaker's own opinion; 3. Petrylak D et al. Presented at ASCO 2024. Abstract 4503; 4. Brower B et al. *Front Oncol* 2024;14:1326715.

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Best-practice sharing: Practical approaches to patient care – Part 2

Dr Phichai Chansriwong

Medical Oncologist, Ramathibodi Hospital, Bangkok, Thailand

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Patient case study: Monitoring and management of cutaneous toxicities

Mr N

- Thai, male
- **Age: 75** years
- **ECOG PS: 1**
- **GFR: 35** mL/min
- **BMI: 24** kg/m^2
- **HbA1c:** 6.2 mmol/mol

Lifestyle: Active

Employment status: Retired

Family history of cancer: Sister with breast cancer

Comorbidities:
- Diabetes mellitus
- Hypertension
- CKD Stage 3

Concomitant medications: Glipizide BID (one tablet before meals)

Any other relevant medical history: N/A

Fictitious patient case study created for illustrative purposes.

BID, twice daily; BMI, body mass index; CKD, chronic kidney disease; ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate; HbA1c, glycated haemoglobin; N/A, not applicable.

Treatment initiation, dosage, and schedule

Jul 2021

Initial presentation

Gross haematuria

- TCC at right ureter
- Operation: right radical nephroureterectomy
- Invasive papillary UC, high grade involved in periureteric fat, 2 cm in thickness
- LN 0/2, free margin

Sep 2021

Further investigations

- Consulted for adjuvant chemotherapy
- Urine cytology positive for high-grade TCC

Nov 2021

Further investigations

- CT scan: Positive new paraaortic node 1.6 cm, aortocaval, bilateral common iliac node
- Cystoscopy + TURBT: Papillary TCC, high grade, no muscularis propria invasion

Dec 2021–Feb 2022

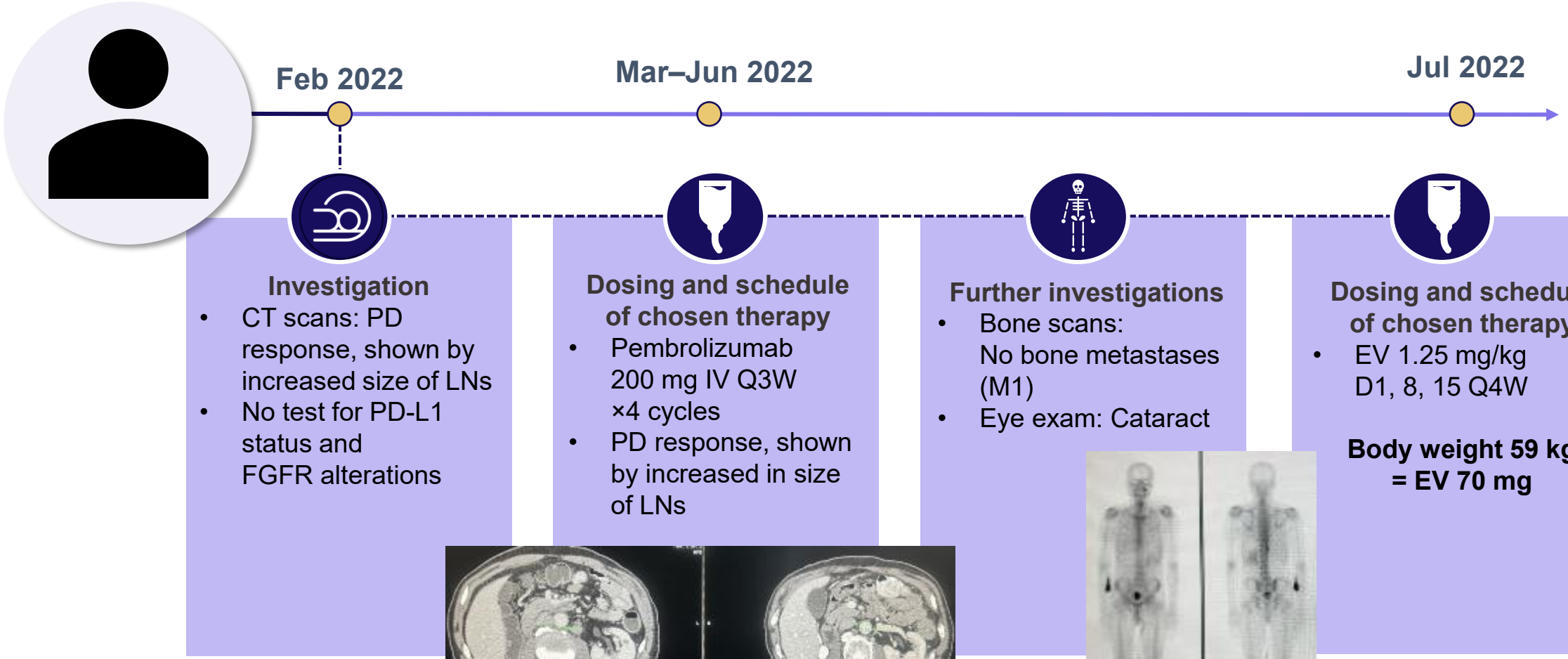
Dosing and schedule of chosen therapy

- Gemcitabine 1000 mg/m^2 and carboplatin AUC 5 ×4 cycles

Fictitious patient case study created for illustrative purposes.

AUC, area under the curve; CT, computed tomography; LN, lymph node; TCC, transitional cell carcinoma; TURBT, transurethral removal of bladder tumour; UC, urothelial carcinoma.

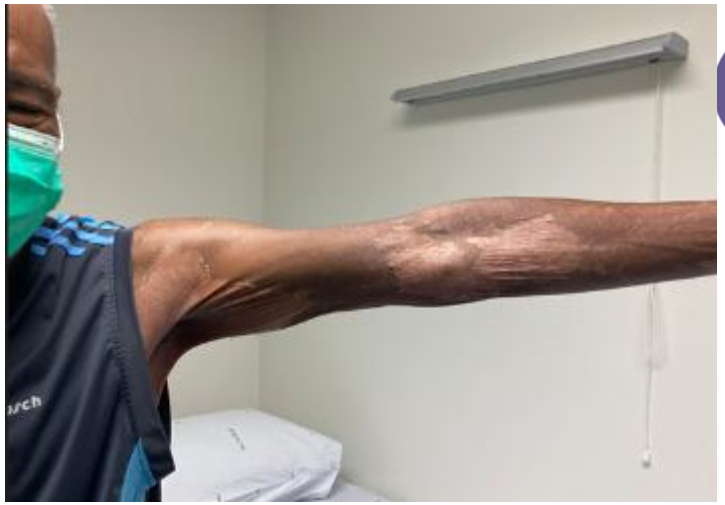
Treatment initiation, dosage, and schedule

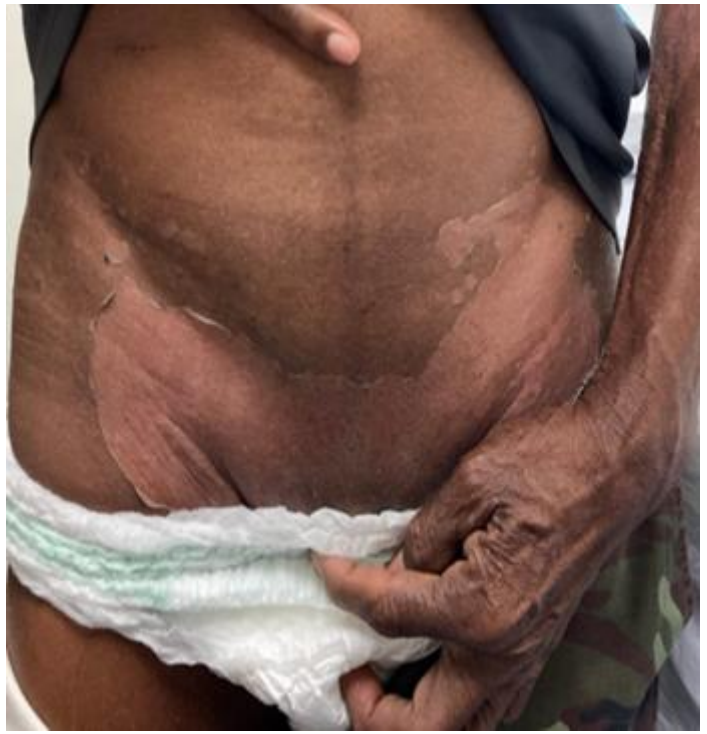


Fictitious patient case study created for illustrative purposes.
Images provided by Dr Phichai with permission.
CT, computed tomography; D, Day; EV, enfortumab vedotin; FGFR, fibroblast growth factor receptor; IV, intravenous; LN. lymph node; PD, progressive disease; PD-L1, programmed cell death ligand 1; Q3W, every 3 weeks; Q4W, every 4 weeks.

AE presentation

- **Cycle 2, Day 8:** The patient had skin lesions, mostly on skin fold. Originated with skin redness and developed to bullous lesions
- **Dermatologist diagnosed SDRIFE:**
  Well-defined symmetrical V-shaped erythematous (red) rash of the gluteal region or groin.
  There is often involvement of at least one other skin fold or flexural area, such as the armpit and behind the knees





Fictitious patient case study created for illustrative purposes.
Images provided by Dr Phichai with permission.
AE, adverse event; SDRIFE, symmetrical drug-related intertriginous and flexural exanthema.

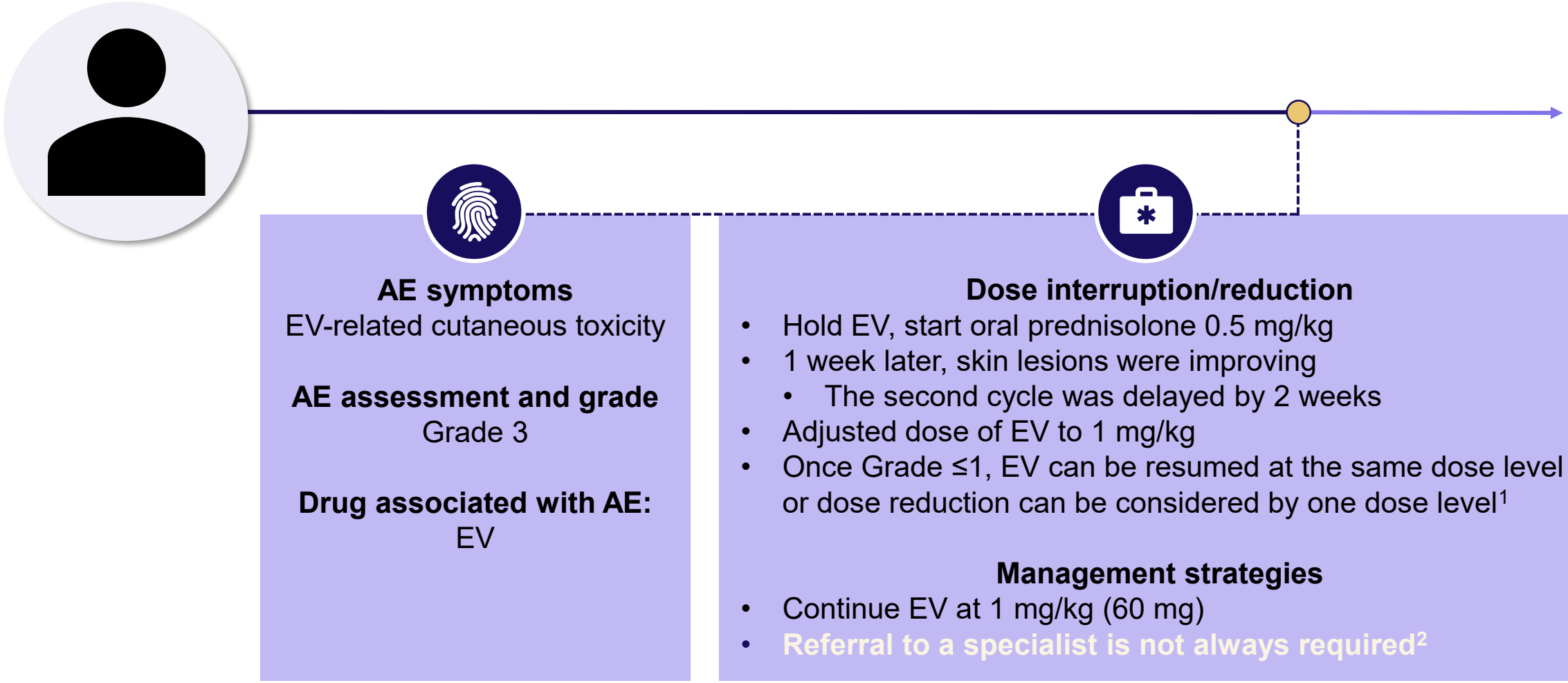
Question for the audience

What treatment approach would you favour for this patient?

- **A** Withhold EV until Grade ≤1
- **B** Topical agents
- **C** Referral to a dermatologist
- **D** Permanently discontinue EV

EV, enfortumab vedotin.

AE presentation and management: EV-related cutaneous toxicity



AE symptoms
EV-related cutaneous toxicity

AE assessment and grade
Grade 3

Drug associated with AE:
EV

Dose interruption/reduction

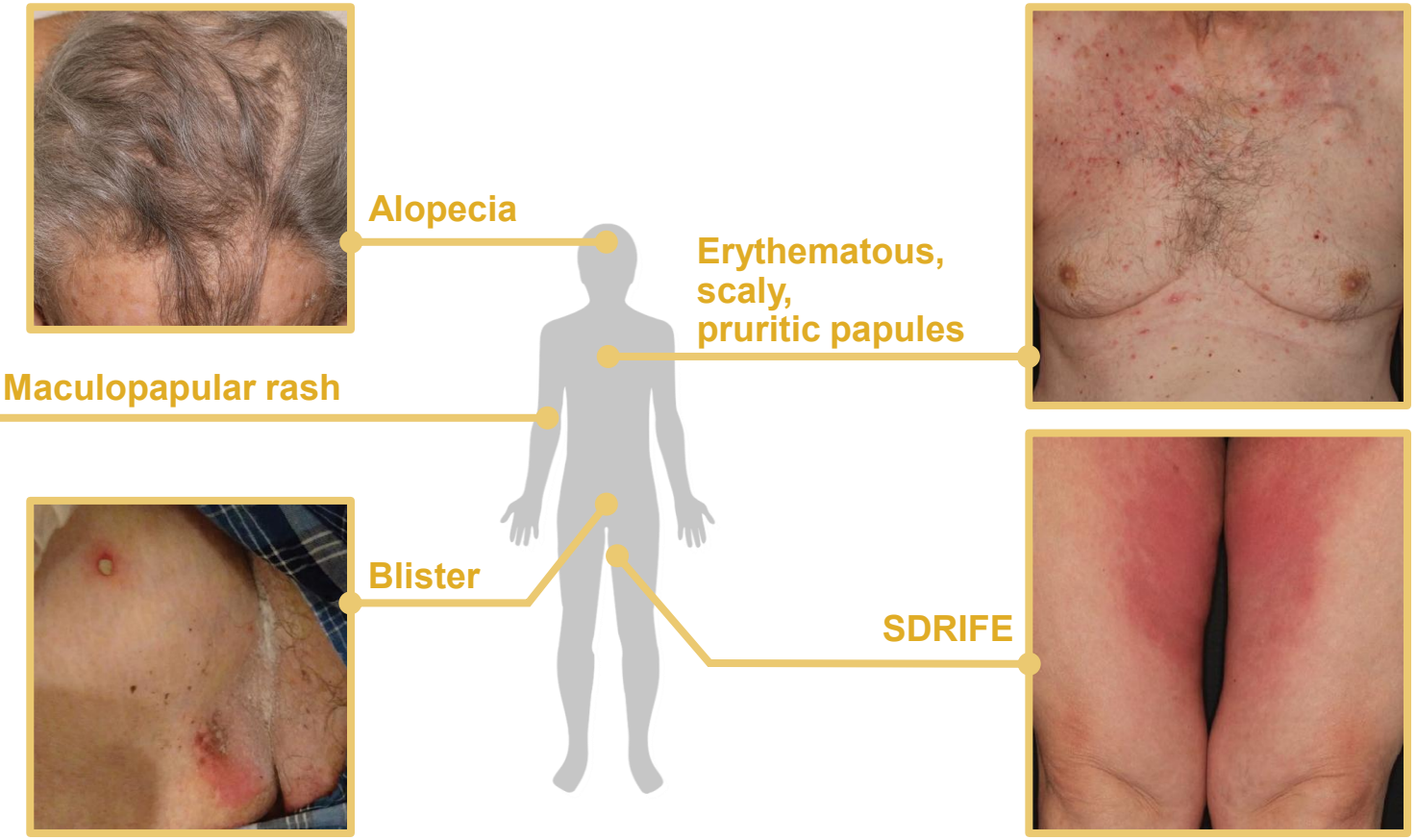
- Hold EV, start oral prednisolone 0.5 mg/kg
- 1 week later, skin lesions were improving
  - The second cycle was delayed by 2 weeks
- Adjusted dose of EV to 1 mg/kg
- Once Grade ≤1, EV can be resumed at the same dose level or dose reduction can be considered by one dose level[1]

Management strategies

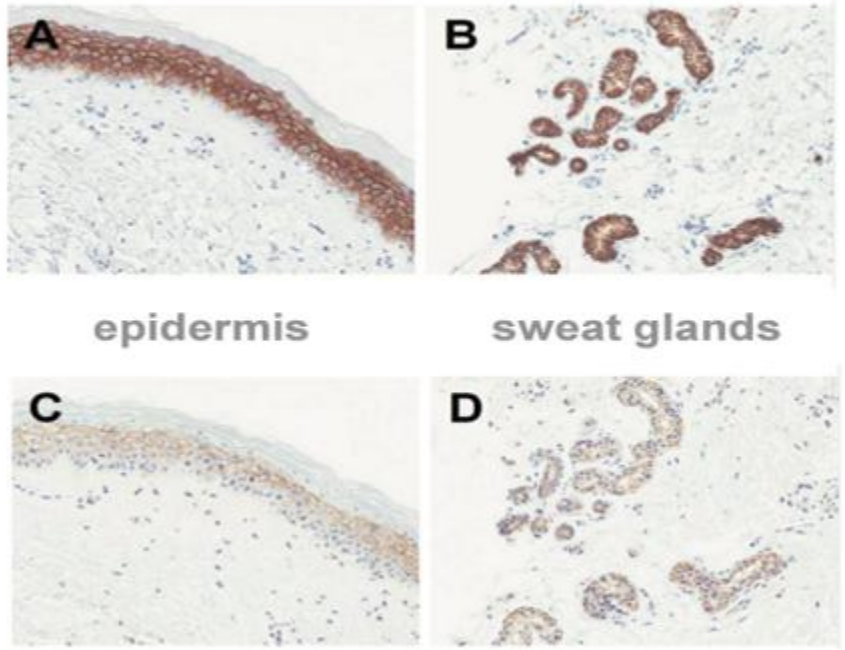
- Continue EV at 1 mg/kg (60 mg)
- **Referral to a specialist is not always required[2]**

Fictitious patient case study created for illustrative purposes.
AE, adverse event; EV, enfortumab vedotin.
1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9.

Cutaneous toxicities associated with EV may vary in morphology, distribution, and associated symptoms



Expression of Nectin-4 in the skin*



Images reproduced from 'Management of Dermatologic Events Associated With the Nectin-4-directed Antibody-Drug Conjugate Enfortumab Vedotin' Lacouture ME et al. *Oncologist* 2022;27:e223–e232. Available at: https://academic.oup.com/oncolo/article/27/3/e223/6537593?login=false. By CC: https://creativecommons.org/licenses/by-nc/4.0/

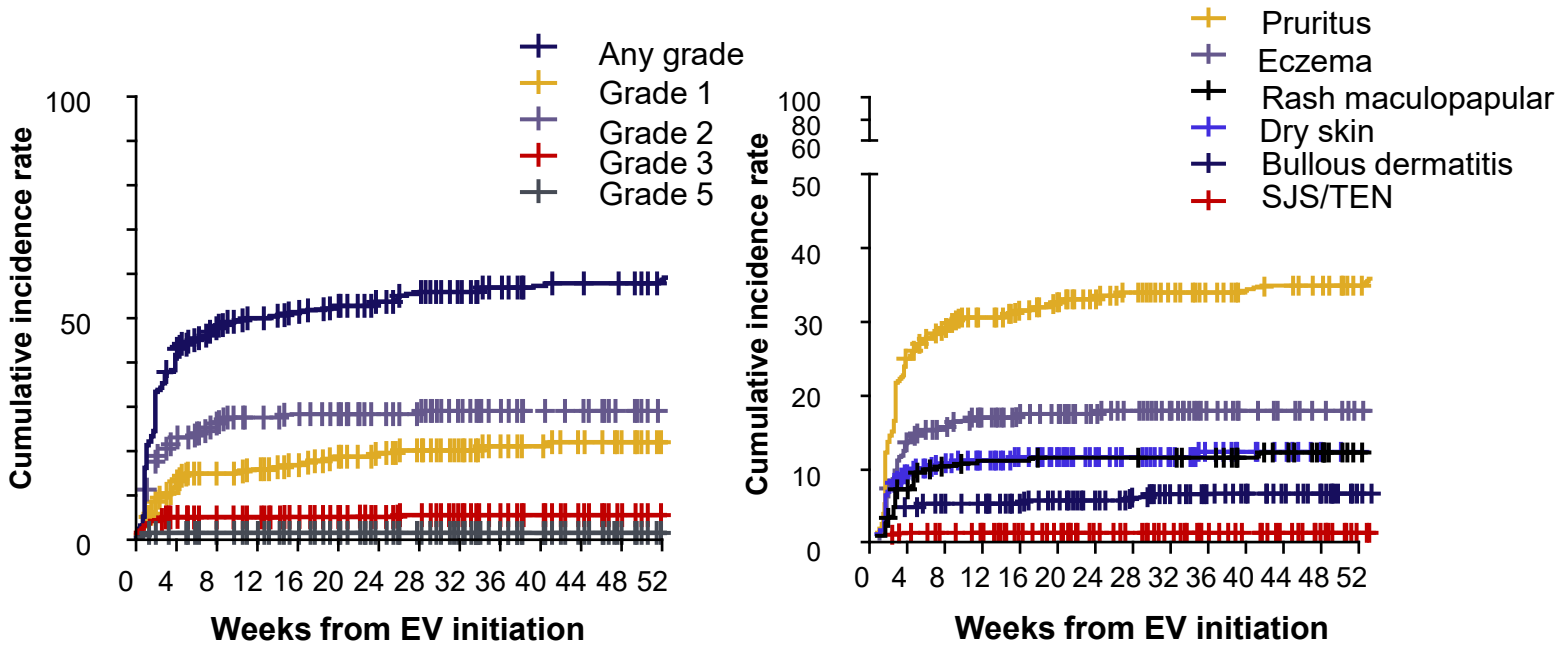
*Positive Nectin-4 staining (brown) by immunohistochemistry.

EV, enfortumab vedotin; SDRIFE, symmetrical drug-related intertriginous and flexural exanthema.

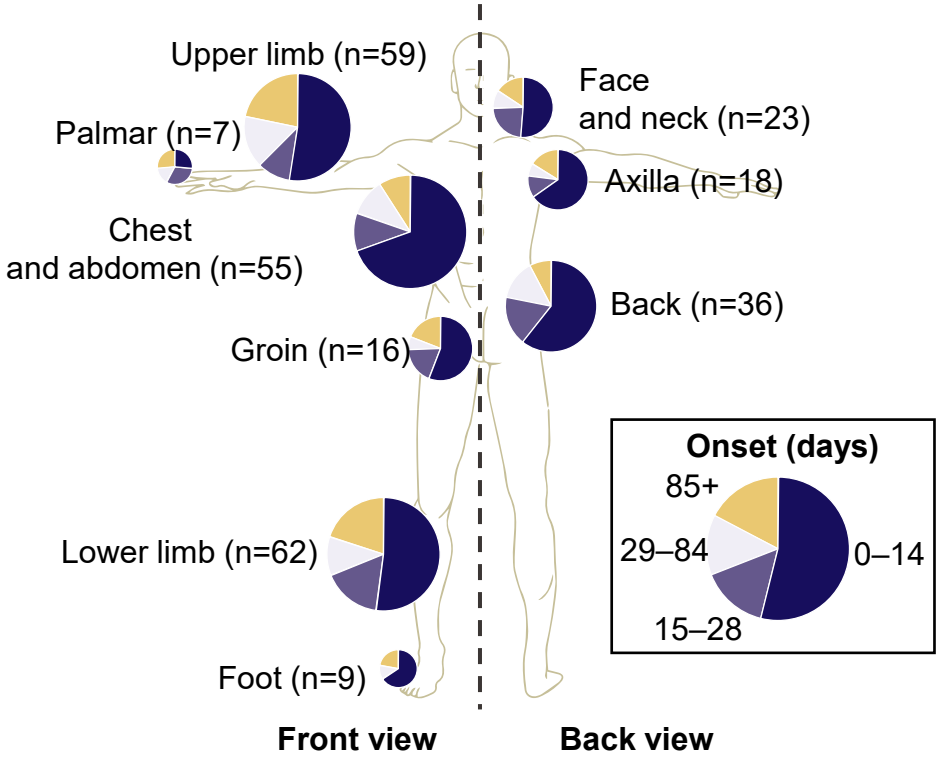
Lacouture ME et al. *Oncologist* 2022;27:e223–e232.

EV-related cutaneous toxicities have a characteristic time to onset and site occurrences

Maximum grade and EVRCT type



Onset and occurrence by site



EV, enfortumab vedotin; EVRCT, EV-related cutaneous toxicity; SJS, Stevens–Johnson syndrome; TEN, toxic epidermal necrolysis.

Kita Y et al. *ESMO Real World Data and Digital Oncology* 2025;7:100094.

Cutaneous toxicities such as maculopapular rash and SJS can be graded according to the CTCAE

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Rash maculopapular: A disorder characterised by the presence of macules and papules. Also known as morbilliform rash, it is one of the most common cutaneous adverse events, frequently affecting the upper trunk, spreading centripetally and associated with pruritus				
Macule/papules covering 10–30% BSA with or without symptoms*	Macule/papules covering 10–30% BSA with or without symptoms;* limiting instrumental ADLs; rash covering >30% BSA with or without mild symptoms	Macule/papules covering >30% BSA with moderate or severe symptoms; limiting self-care ADLs	N/A	N/A
SJS: A disorder characterised by less than 10% total BSA separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and mucous membranes				
N/A	N/A	Skin sloughing covering <10% BSA with associated signs†	Skin sloughing covering 10–30% BSA with associated signs†	Death

*Pruritus, burning, and tightness; †Erythema, purpura, epidermal detachment, and mucous membrane detachment.
ADLs, activities of daily living; BSA, body surface area; CTCAE, Common Terminology Criteria for Adverse Events; N/A, not applicable; SJS, Stevens–Johnson syndrome.
US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025.

Management of severe cutaneous toxicities associated with EV includes dose reduction and treatment interruption

Management of skin toxicities associated with EV per SmPC*

<table>
<tr><th rowspan="2">Management strategy</th><th rowspan="2">Grade 1 (mild)</th><th colspan="2">Grade 2 (moderate)</th><th colspan="2">Grade 3 (severe)</th><th rowspan="2">Grade 4 (life-threatening)</th></tr>
<tr><th>Stable/no fever</th><th>Worsening/fever</th><th>First event</th><th>Recurrent event</th></tr>
<tr><td>EV dose modification</td><td colspan="2">None[1]</td><td colspan="2">Withhold EV until Grade ≤1, then resume at the same/ one level lower dose[1]</td><td colspan="2">Permanently discontinue EV[1]</td></tr>
<tr><td rowspan="2">Pharmacological intervention</td><td colspan="3">If indicated: topical corticosteroids, topical antibiotics, topical/oral antihistamines[1–3]</td><td colspan="3" rowspan="2">Treat with systemic corticosteroids[2,3]</td></tr>
<tr><td>Consider creams/ emollients[2,3]</td><td colspan="2">Consider anti-infective agents[3]</td></tr>
<tr><td>Referral</td><td colspan="2" rowspan="2">None[1]</td><td colspan="3">Consider referral to dermatologist[1]</td></tr>
<tr><td colspan="3">Admit to hospital for specialised care[3]</td></tr>
</table>

For suspected SJS, TEN, or bullous lesions, immediately withhold EV and refer to specialised care[1]

*Grading according to the CTCAE.[2]

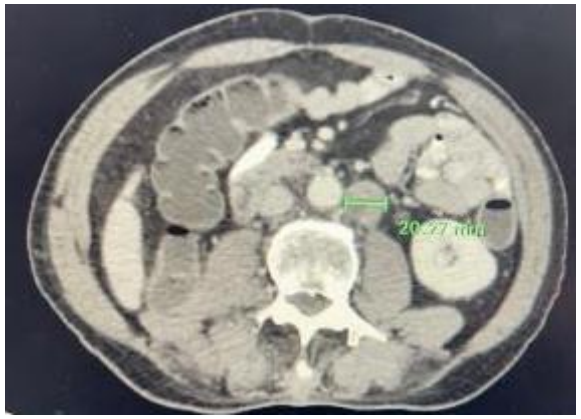
CTCAE, Common Terminology Criteria for Adverse Events; EV, enfortumab vedotin; SJS, Stevens–Johnson syndrome; SmPC, Summary of Product Characteristics; TEN, toxic epidermal necrolysis.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9; 3. Lacouture ME et al. *Oncologist* 2022;27:e223–e232.

Long-term response to treatment [1/3]

Jul 2022

Jan 2023

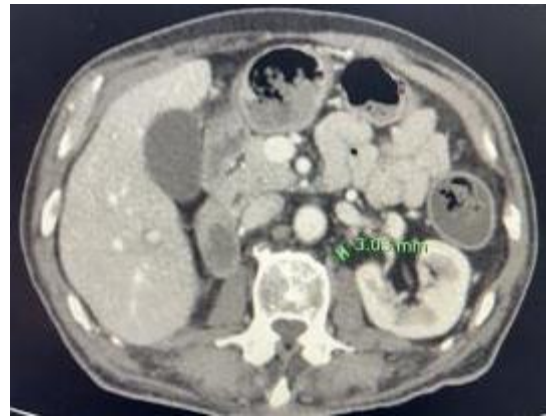


Jul 2022

Imaging

CT scan:
Paraaortic LN,
aortocaval LN
subcentimetre

- CR response
- Continue EV?

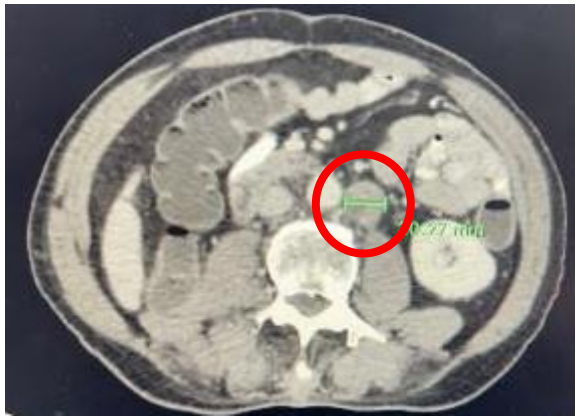


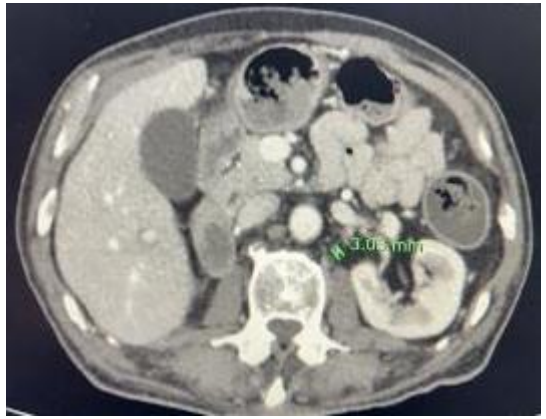
Jan 2023

Fictitious patient case study created for illustrative purposes.
Images provided by Dr Phichai with permission.
CR, complete response; CT, computed tomography; EV, enfortumab vedotin; LN, lymph node.

Long-term response to treatment [2/3]

Post Cycle 6
CT scan in Jan 2023: CR response





Jul 2022 **Jan 2023**

Post 12th cycle

CT scan in Jul 2023:
- Still CR response
- **Developed Grade 2 neuropathy – stopped EV**

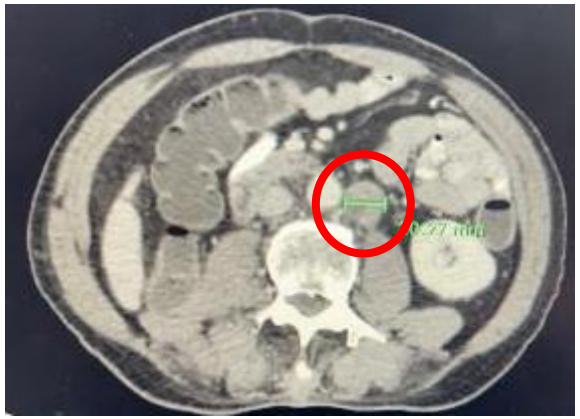
Guidance for Grade 2 PN[1]
- Withhold until Grade ≤1
- For first occurrence, resume treatment at the same dose level
- For a recurrence, withhold until Grade ≤1, then resume treatment reduced by one dose level

Fictitious patient case study created for illustrative purposes.
Images provided by Dr Phichai with permission.
CR, complete response; CT, computed tomography; EV, enfortumab vedotin; PN, peripheral neuropathy.
1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

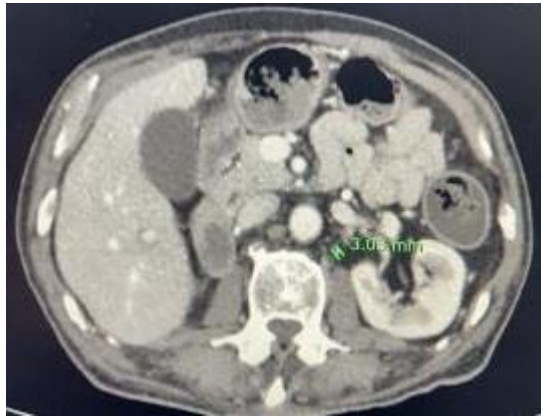
Long-term response to treatment [3/3]

Jul 2022 — Jan 2023 — Jul 2023 — May 2025

Post Cycle 6
CT scan in Jan 2023: CR response



Jul 2022

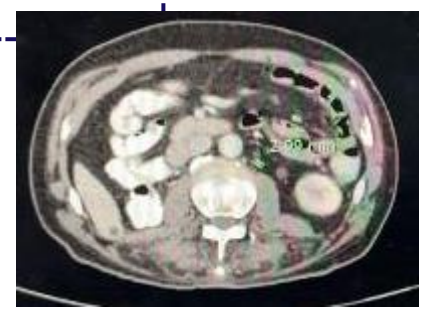


Jan 2023

Post 12th cycle

CT scan in Jul 2023:
- Still CR response
- **Developed Grade 2 neuropathy – stopped EV**

Last CT scans on 16 May 2025:
- **CR**



No change of multiple tiny LNs along paraaortic and aortocaval regions
Target lesions:
- Paraaortic node L2, 3.6 mm
- Paraaortic node L3, 4.4 mm
- Aortocaval node L2, 2.0 mm

Non-target lesions:
- Paraaortic node L2, 3.0 mm
- Aortocaval node L4, 2.9 mm

Fictitious patient case study created for illustrative purposes.
Images provided by Dr Phichai with permission.
CR, complete response; CT, computed tomography; EV, enfortumab vedotin; LN, lymph node.

Summary

EV was significantly associated with cutaneous toxicities, occurring in 57% of EV-treated patients (including maculopapular rash and pruritus), with 14% of patients experiencing Grade 3–4 reactions. However, proactive management strategies can help to ensure that patients continue to maximise clinical benefits with EV[1]

It is important to educate patients about the potential risk and closely monitor patients for the emergence of any skin reaction, such as SJS/TEN, which can be fatal. Patients should be instructed to immediately report the EV-related cutaneous toxicity, especially in the early cycles of treatment, so that it can be managed effectively without requiring treatment discontinuation[1,2]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[3]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilised to manage AEs, to ensure that patients receive optimal treatment outcomes[1]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; SJS, Stevens–Johnson syndrome; TEN, toxic epidermal necrolysis.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Lacouture ME et al. *Oncologist* 2022;27:e223–e232; 3. Brower B et al. *Front Oncol* 2024;14:1326715.

Thank you

Ramathibodi Hospital
Bangkok, Thailand

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PI, Prescribing Information

Genitourinary Masterclass

Best-practice sharing: Practical approaches to patient care – Part 2

Professor Yüksel Ürün

Ankara University School of Medicine, Ankara

EV as first-line therapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Combination therapy with pembrolizumab.

EV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor and have received a platinum-containing chemotherapy.

EV, enfortumab vedotin.
PADCEV® (enfortumab vedotin). Prescribing Information.
July 2025 | MAT-KR-PAD-2025-00087

PADCEV®
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

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Such information, views and opinions of the presenter do not necessarily reflect the information, views and opinions of Astellas Pharma Ltd. Astellas Pharma Ltd. does not recommend the use of any product in any different manner than as described in the local approval information, and complies with all applicable laws, regulations, and company policies.

Patient case study: Monitoring and management of peripheral neuropathy

Ms. Fatma

- White, female
- **Age: 65** years
- **ECOG PS: 1**
- **GFR: 54** mL/min
- **BMI: 22** kg/m^2
- **HbA1c: 5.6** mmol/L

Lifestyle: Active, no history of smoking or alcohol

Employment status/job: Retired accountant

Family history of cancer: Mother had breast cancer

Comorbidities
- Hypertension

Concomitant medications
- ACE inhibitor

Any other relevant medical history: None

Fictitious patient case study created for illustrative purposes.

ACE, angiotensin-converting enzyme; BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; GFR, glomerular filtration rate; HbA1c, glycated hemoglobin; PS, performance status.

Diagnosis

May 2021

Apr 2021

Initial presentation

- Hematuria
- Flank pain

CT and MRI

Mass detected in the right renal pelvis

PET/CT

- Involvement detected in the right renal pelvis, intra-abdominal lymph nodes, left supraclavicular lymph node, and segment 7 of the liver

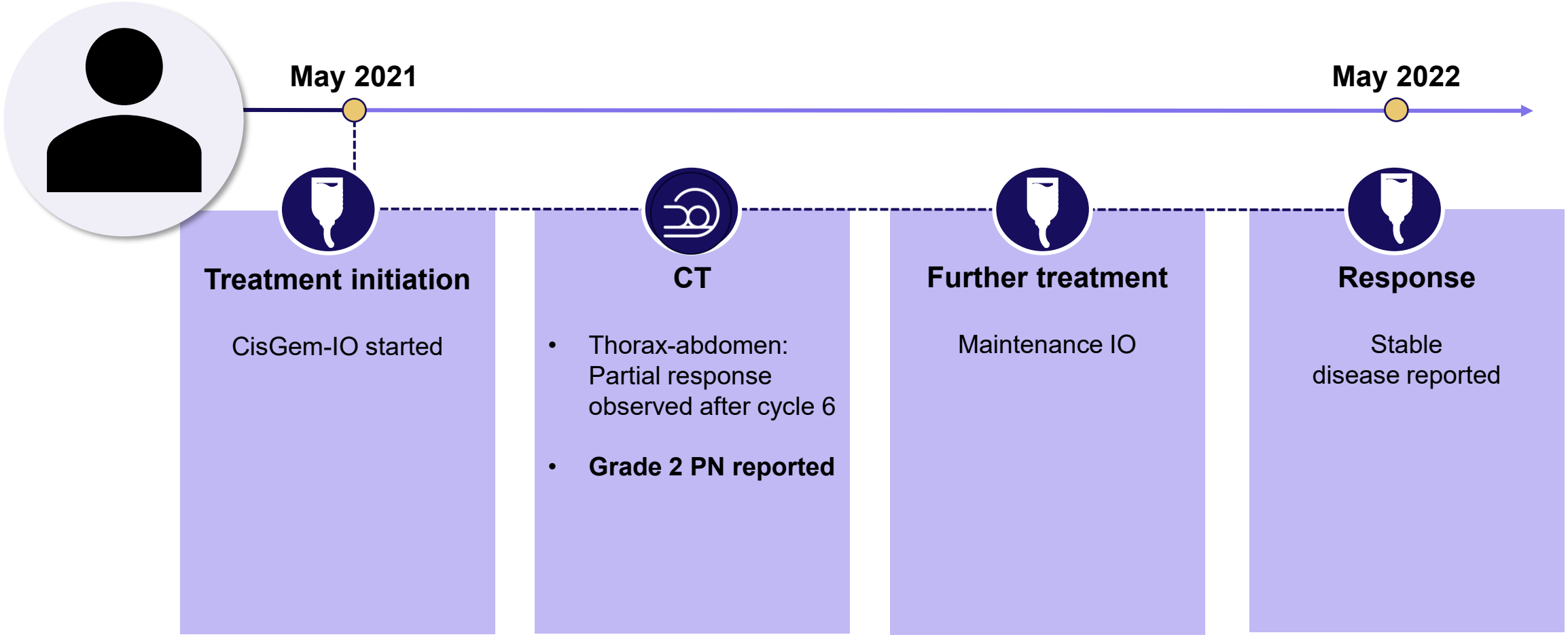
Dynamic liver MRI

- 17 mm metastatic lesion detected in segment 6 of the liver

Fictitious patient case study created for illustrative purposes.

CT, computed tomography; MRI, magnetic resonance imaging; PET, positron emission tomography.

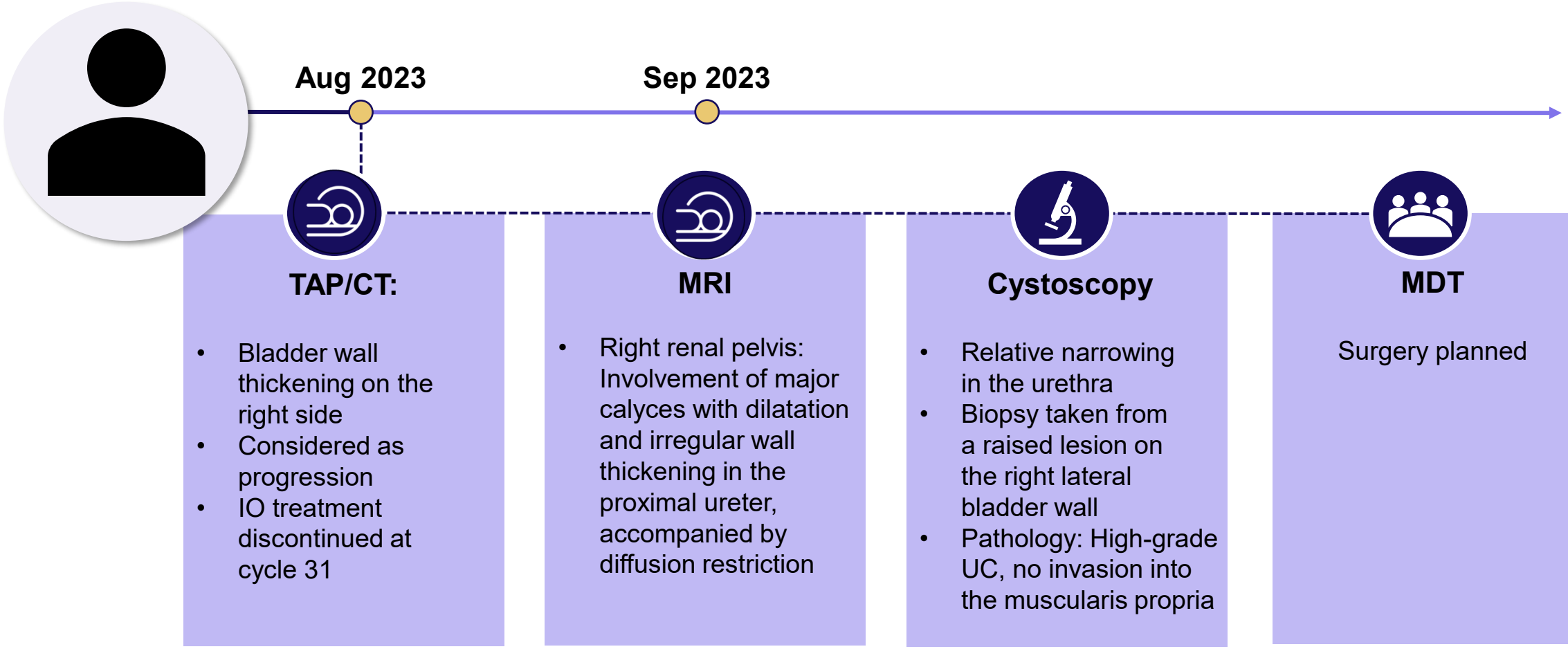
Treatment initiation, dosage, and schedule



Fictitious patient case study created for illustrative purposes.

Cis, cisplatin; CT, computed tomography; Gem, gemcitabine; IO, immunotherapy; PN, peripheral neuropathy.

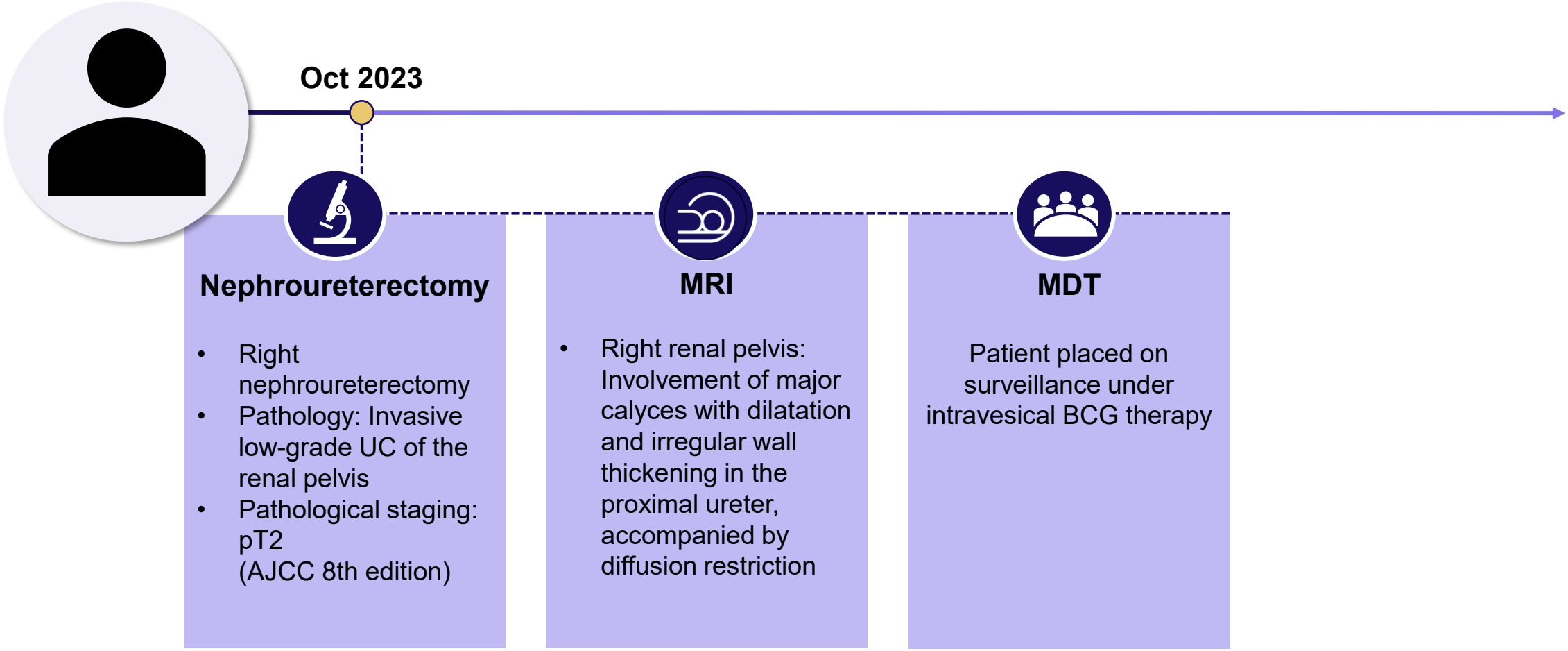
Response to treatment



Fictitious patient case study created for illustrative purposes.

CT, computed tomography; IO, immunotherapy; MDT, multidisciplinary team; MRI, magnetic resonance imaging; TAP, thoracoabdominal pelvic; UC, urothelial carcinoma.

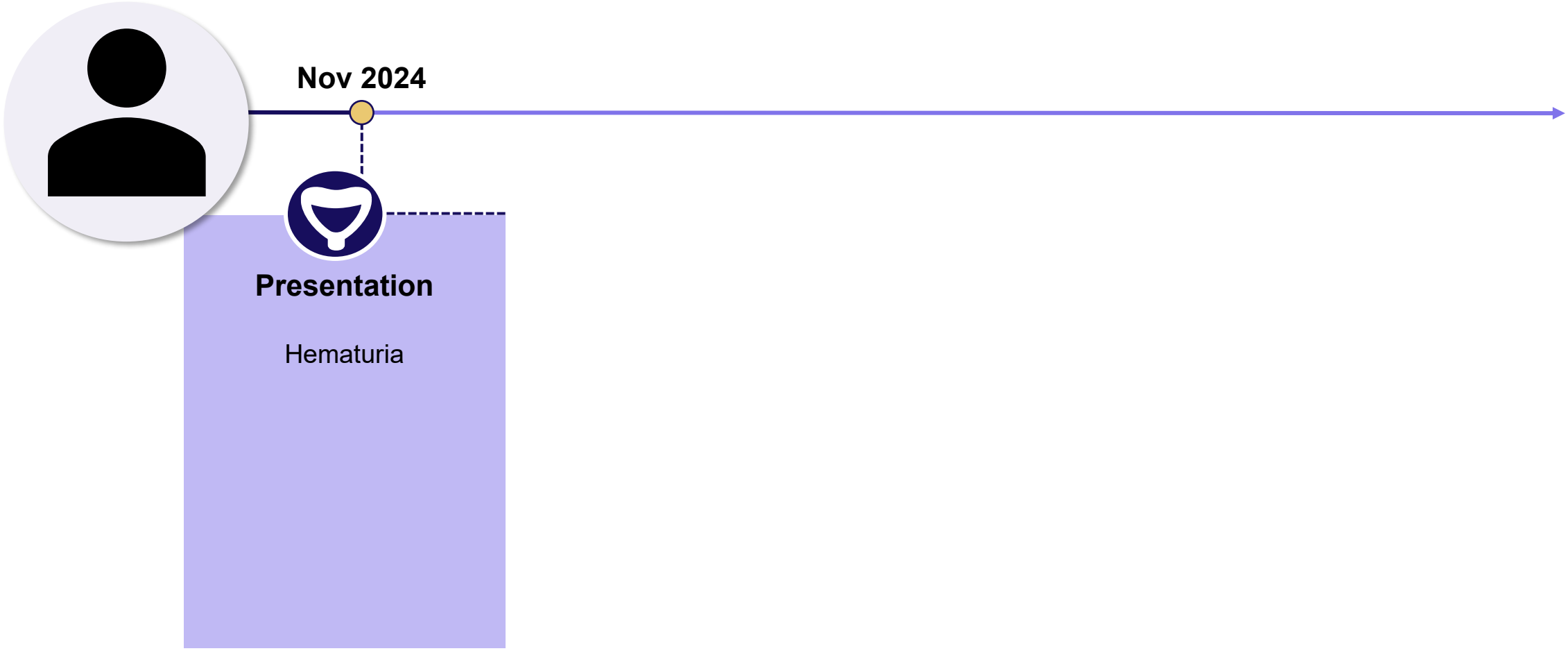
Further investigations



Fictitious patient case study created for illustrative purposes.

AJCC, American Joint Committee on Cancer; BCG, Bacillus Calmette–Guerin; MDT, multidisciplinary team; MRI, magnetic resonance imaging; UC, urothelial carcinoma.

Response to treatment [1/3]



Fictitious patient case study created for illustrative purposes.

Response to treatment [2/3]

PET-CT report summary:

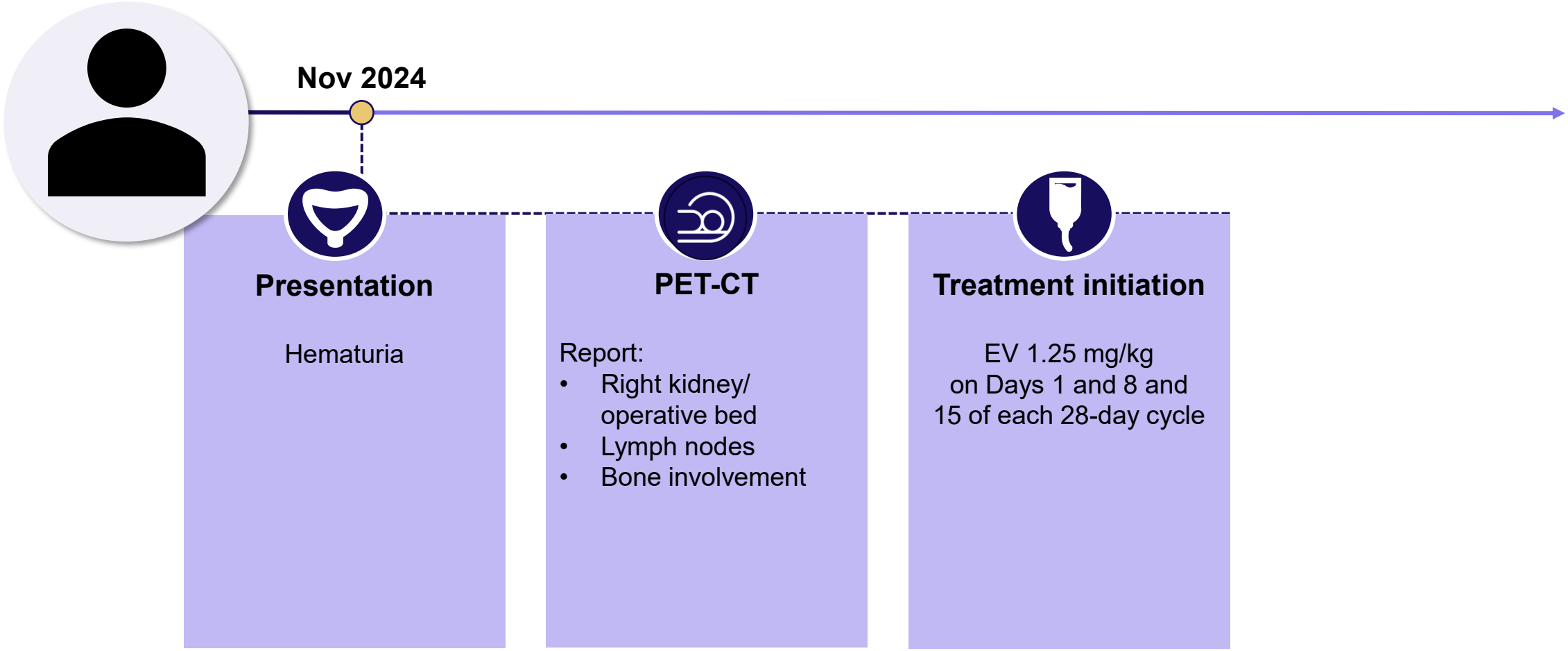
Right kidney/operative bed:
- Multiple nodular soft tissue formations with intense pathological 18F-FDG uptake
- Consistent with local recurrence

Lymph nodes:
- Bilateral paraaortic, paracaval, interaortocaval, and lumbar lymph node
- Multiple left supraclavicular lymph nodes

Bone involvement:
- Right half of the thoracic vertebra (T12)
- Consistent with bone metastasis from primary malignancy

Fictitious patient case study created for illustrative purposes.
CT, computed tomography; FDG, fluorodeoxyglucose; PET, positron emission tomography.

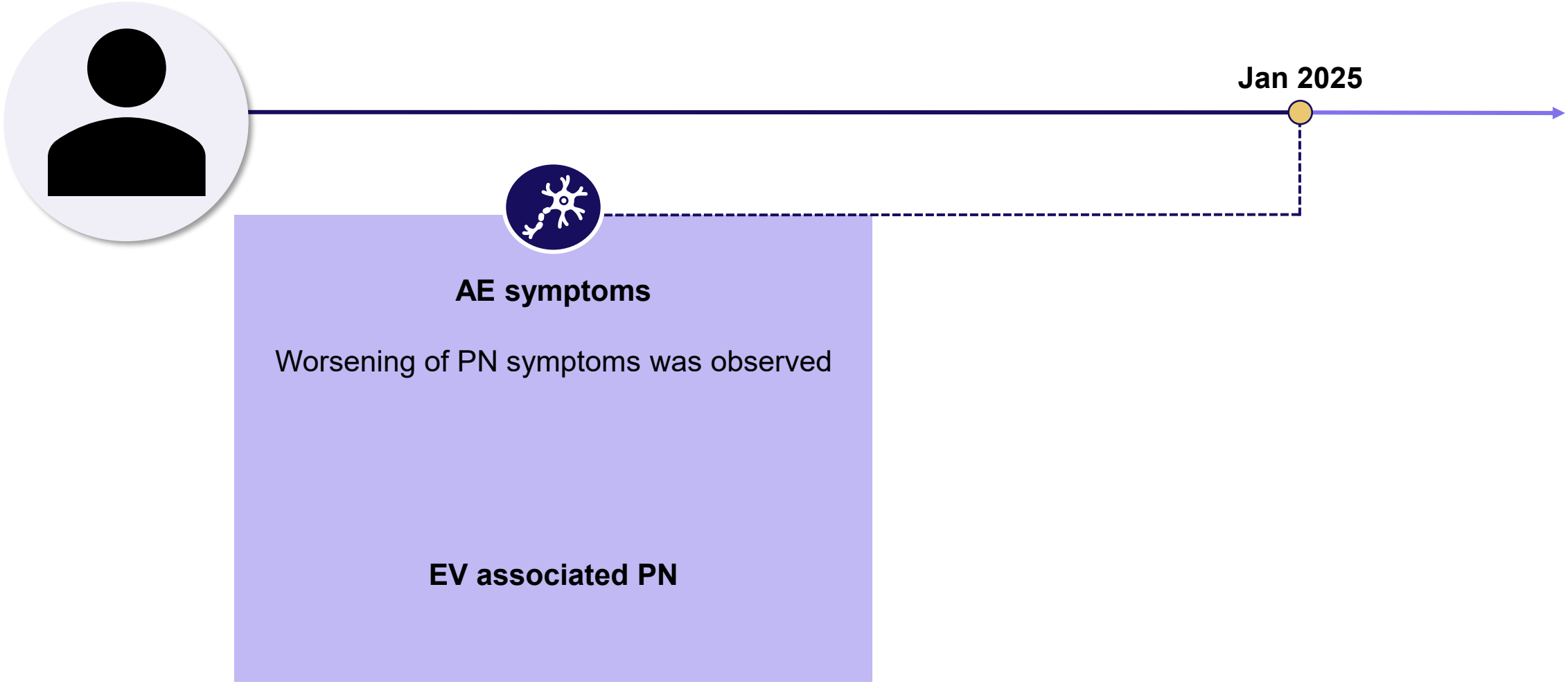
Response to treatment [3/3]



Fictitious patient case study created for illustrative purposes.

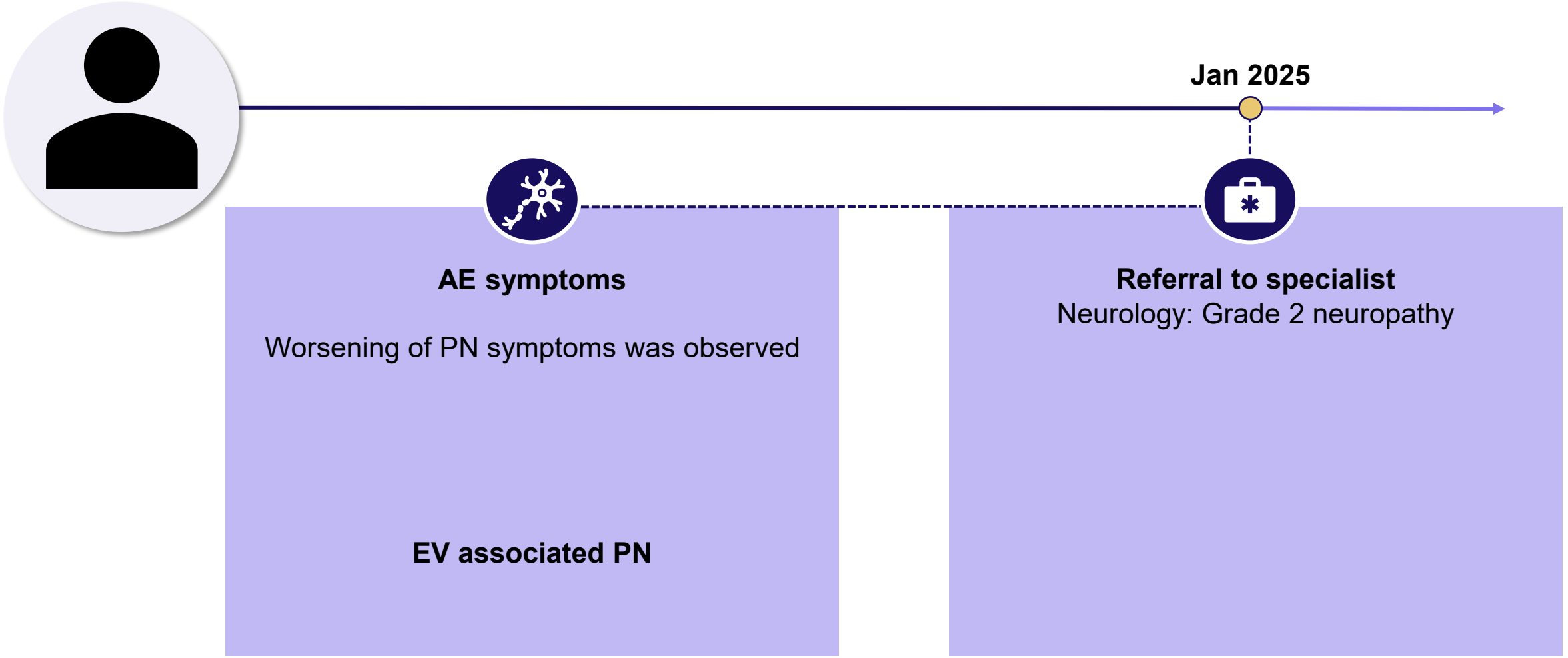
CT, computed tomography; EV, enfortumab vedotin; PET, positron emission tomography.

AE presentation and management



Fictitious patient case study created for illustrative purposes.
AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy.

AE presentation and management



Fictitious patient case study created for illustrative purposes.
AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy.

Question for the audience

How would you approach managing this adverse event?

- **A** Withhold EV until Grade ≤1 and resume at same dose
- **B** Withhold EV until Grade ≤1 and resume at reduced dose
- **C** Permanently discontinue EV
- **D** Other

EV, enfortumab vedotin.

Question for the audience

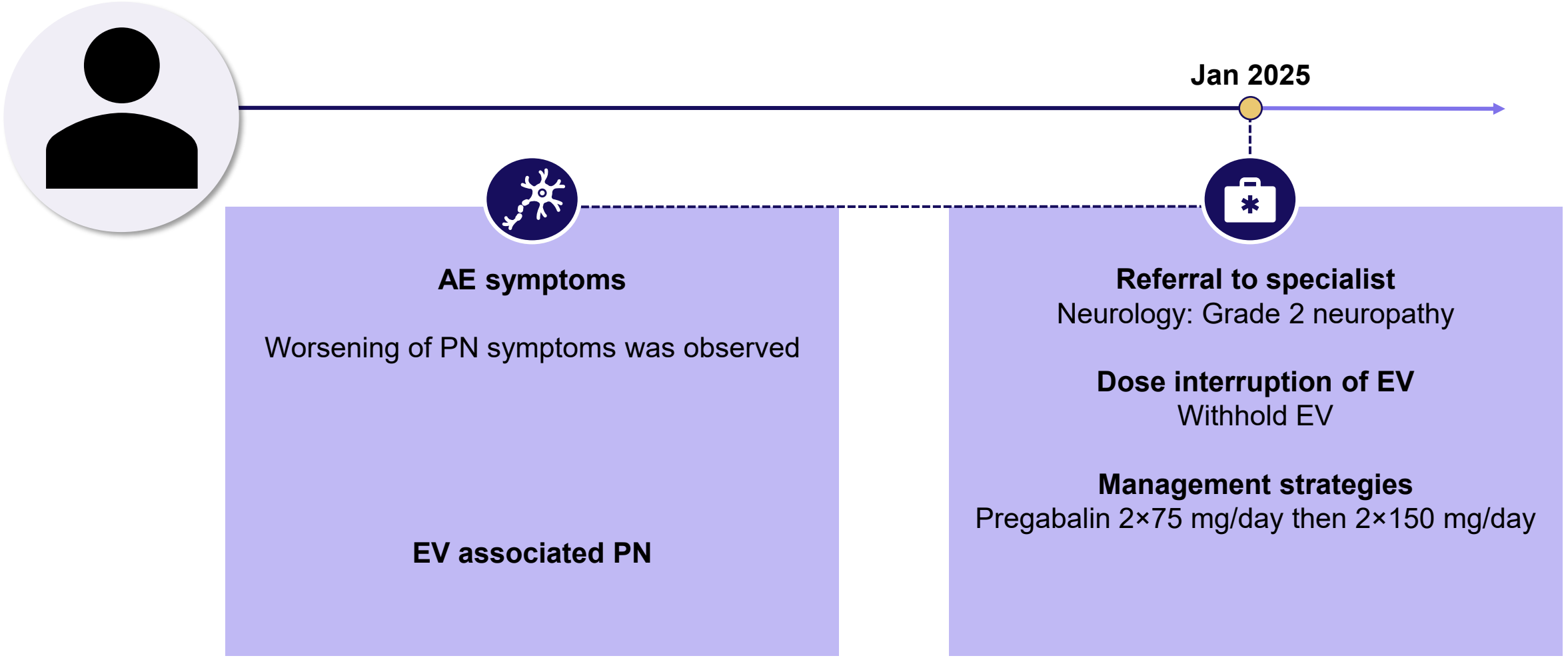
How would you approach managing this adverse event?

- **A** Withhold EV until Grade ≤1 and resume at same dose
- **B** Withhold EV until Grade ≤1 and resume at reduced dose[1]
- **C** Permanently discontinue EV
- **D** Other

EV, enfortumab vedotin.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

AE presentation and management



Fictitious patient case study created for illustrative purposes.

AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy.

Peripheral neuropathy: Classification

Identifying grades[1]

Grade 1

Does not affect day to day activities. Asymptomatic or mild symptoms only

Grade 2

Affects day to day activities such as buttoning up clothes, holding cutlery while eating, and holding small objects

CTCAE (neurotoxicity)[1]

AE	Grade 1	Grade 2	Grade 3	Grade 4
Peripheral sensory neuropathy	Asymptomatic	Moderate symptoms; limiting instrumental ADL*	Severe symptoms; limiting self-care ADL†	Life-threatening consequences; urgent intervention indicated

*Instrumental ADLs include preparing meals, shopping, using the telephone, and managing money; †Self-care ADLs include bathing, dressing, using the toilet, and taking medications.
ADL, activities of daily living; AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events.

US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025.

Peripheral neuropathy is a common AE associated with EV

Incidence of PN associated with EV[1]

Across clinical studies of 793 patients receiving EV as monotherapy, PN occurred in 53% of patients

- 5% of patients experienced severe PN (Grade 3 or 4)
- Median time to onset of Grade ≥2 PN was 5 months

PN is a common AE associated with EV

Incidence of peripheral sensory neuropathy in EV-301*[2,3]

TRAEs, n (%)*	EV (n=296)		Chemotherapy (n=291)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any AE	278 (93.9)	155 (52.4)	267 (91.8)	147 (50.5)
Peripheral sensory neuropathy	**103 (34.8)**	**15 (5.1)**	**63 (21.6)**	**6 (2.1)**

*Median follow-up of 24 months.[2]

AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy; TRAE, treatment-related adverse event.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Rosenberg JE et al. *Ann Oncol* 2023;34:1047–1054; 3. Rosenberg JE et al. *Ann Oncol* 2023;34:1047–1054 (supplementary).

SmPC management guidance

AESI	Severity	Dose modification
Peripheral neuropathy	**Grade ≥3**	Permanently discontinue
	Grade 2	• Withhold until Grade ≤1 • For first occurrence, resume treatment at the same dose level • For a recurrence, withhold until Grade ≤1, then resume treatment reduced by one dose level

Dose reduction schedule

Starting dose
1.25 mg/kg*
up to 125 mg

First dose reduction
1.00 mg/kg
up to 100 mg

Second dose reduction
0.75 mg/kg
up to 75 mg

Third dose reduction
0.50 mg/kg
up to 50 mg

*Up to a maximum of 125 mg for patients weighing ≥100 kg.
AESI, adverse event of special interest; SmPC, Summary of Product Characteristics.
PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

AE management

Feb 2025

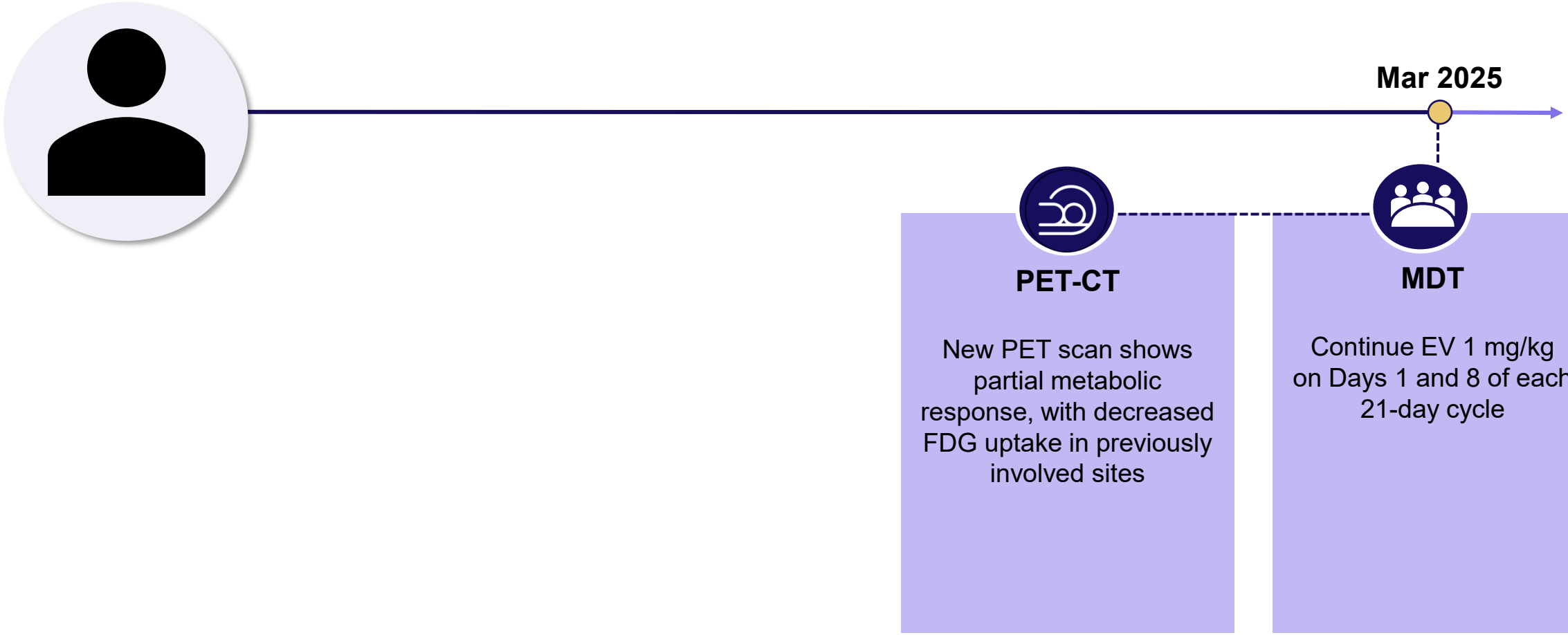
PN returned to Grade ≤1

Management strategies:
Continue pregabalin 2×75 mg/day

Subsequent treatment:
EV 1 mg/kg
on Days 1 and 8 of each 21-day cycle

Fictitious patient case study created for illustrative purposes.
AE, adverse event; EV, enfortumab vedotin; PN, peripheral neuropathy.

Long-term response to treatment

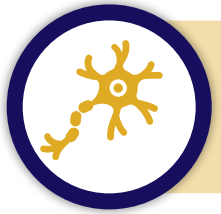


Fictitious patient case study created for illustrative purposes.

CT, computed tomography; EV, enfortumab vedotin; FDG, fluorodeoxyglucose; MDT, multidisciplinary team; PET, positron emission tomography.

Case summary

Patient experienced recurrent upper tract UC, post chemotherapy, IO, and nephroureterectomy. The patient then began treatment with EV after development of nodal and bone metastases



A partial metabolic response was observed on follow-up PET-CT. The patient's pre-existing PN worsened but was resolved, and treatment continued with supportive care

EV demonstrated clinical benefits and was tolerable with appropriate dose modification and AE management, despite comorbidities and prior therapies

Fictitious patient case study created for illustrative purposes.

CT, computed tomography; EV, enfortumab vedotin; IO, immunotherapy; PET, positron emission tomography; PN peripheral neuropathy; UC, urothelial carcinoma.

Summary

PN is a frequent, dose-limiting toxicity associated with EV use; however, proactive management strategies can help to ensure that patients continue to maximize clinical benefits with EV[1]

Early recognition of treatment-emergent PN and prompt intervention with the use of dose modifications provides the best chance for resolution, without impacting the ability to maintain response to EV. There are no medications specifically recommended for managing EV-induced PN, favoring non-pharmacological interventions[1,2]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[3]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilized to manage AEs, to ensure that patients receive optimal treatment outcomes[1]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; PN, peripheral neuropathy.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 2. Speaker's own opinion; 3. Brower B et al. *Front Oncol* 2024;14:1326715.

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Genitourinary Masterclass

Best-practice sharing: Practical approaches to patient care – Part 2

Dr Alejo Rodriguez-Vida, MD, PhD

Consultant Medical Oncologist, Genitourinary Cancer Unit & Early Drug Development Unit; Associate Professor, Pompeu Fabra University Barcelona, Hospital del Mar, Barcelona, Spain

EV as first-line therapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Combination therapy with pembrolizumab.

EV as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 or programmed death-ligand 1 inhibitor, and have received a platinum-containing chemotherapy

EV, enfortumab vedotin.
PADCEV® (enfortumab vedotin). Prescribing Information

PADCEV®
enfortumab vedotin
Injection for IV infusion 20 mg & 30 mg vials

astellas

July 2025 | MAT-KR-PAD-2025-00089

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Patient case study: Ocular toxicities

- Male
- **Age: 62** years
- **ECOG PS:** 0
- **GFR:** 65 mL/min

Lifestyle: Active smoker, obese

Comorbidities:
- Hypercholesterolemia

Any other relevant medical history:
- Allergic to penicillin
- Moderate COPD

Concomitant medications:
- Statins for hypercholesterolemia

Fictitious patient case study created for illustrative purposes.

COPD, chronic obstructive pulmonary disorder; ECOG PS, Eastern Cooperative Oncology Group performance status; GFR, glomerular filtration rate.

Diagnosis

Feb 2023

Initial presentation

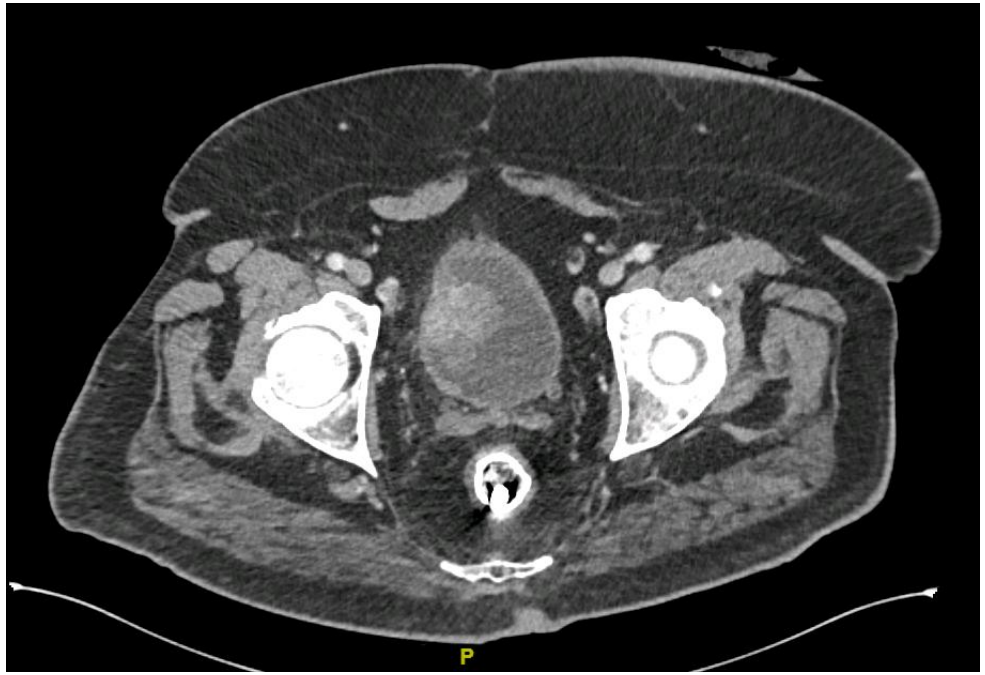
Urinary obstruction

- Bladder USS: bladder mass detected
- TURBT: urothelial carcinoma pT2 (micropapillary differentiation)

Further investigations

CT scan

- No distant metastases or bulky lymph nodes
- TNM: cT2N0M0



Fictitious patient case study created for illustrative purposes.
Images provided by Dr Rodriguez-Vida with permission.
c, clinically staged; CT, computed tomography; p, pathological stage; TNM, tumor, node, metastasis; TURBT, transurethral resection of the bladder; USS, ultrasound scan.

Treatment initiation, dosage, and schedule

Feb 2023

Mar 2023

Initial presentation

Urinary obstruction

- Bladder USS: bladder mass detected
- TURBT: urothelial carcinoma pT2 (micropapillary differentiation)

Further investigations

CT scan

- No distant metastases or bulky lymph nodes
- TNM: cT2N0M0

Chosen therapy

- Neoadjuvant chemotherapy followed by radical cystectomy was decided during the **multidisciplinary tumor board**

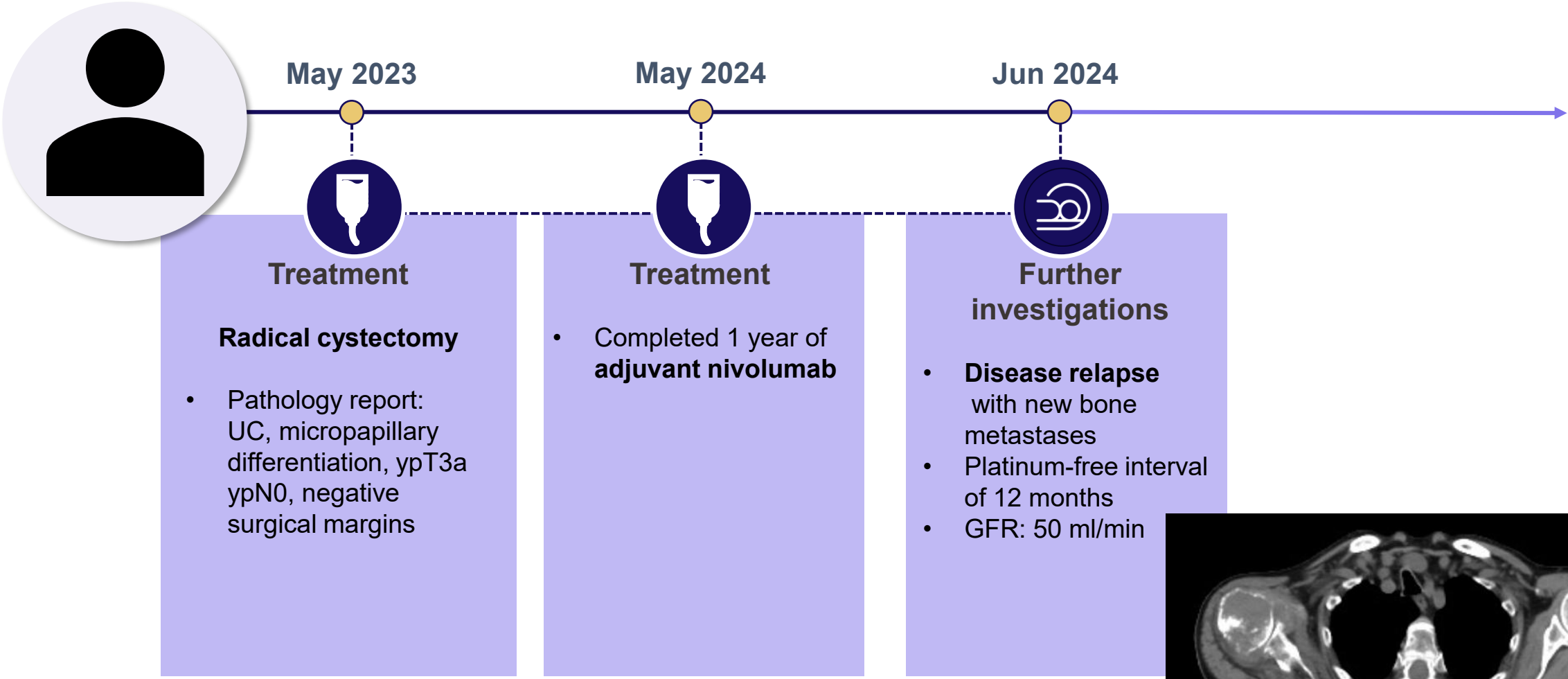
Dosing and schedule

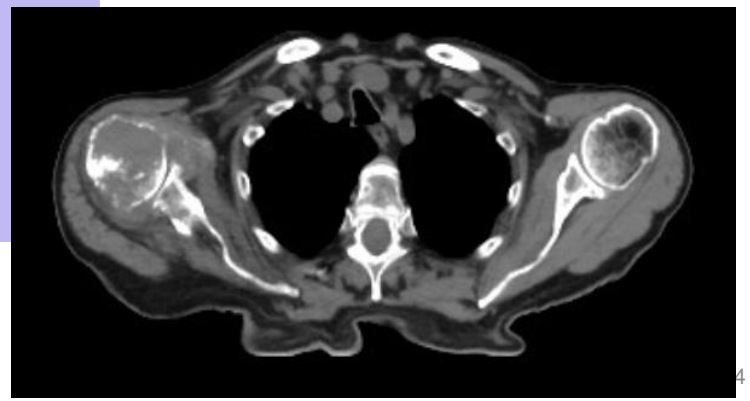
- Started **dose-dense MVAC** (methotrexate 30 mg/m^2, vinblastine 3 mg/m^2, doxorubicin 30 mg/m^2, and cisplatin 70 mg/m^2) every 2 weeks (four cycles) with pegfilgrastim

Fictitious patient case study created for illustrative purposes.

c, clinically staged; CT, computed tomography; MVAC, methotrexate, vinblastine sulfate, doxorubicin hydrochloride, and cisplatin; p, pathological stage; TNM, tumor, node, metastasis; TURBT, transurethral resection of bladder; USS, ultrasound scan.

Surgery and relapse treatment [1/2]





Fictitious patient case study created for illustrative purposes.
Images provided by Dr Rodriguez-Vida with permission.
GFR, glomerular filtration rate; N, node stage; p, pathological stage; UC, urothelial carcinoma; T, tumor stage; y, after neoadjuvant therapy.

Surgery and relapse treatment [2/2]

May 2023

Treatment

Radical cystectomy

- Pathology report: UC, micropapillary differentiation, ypT3a ypN0, negative surgical margins

May 2024

Treatment

- Completed 1 year of adjuvant nivolumab

Jun 2024

Further investigations

- Disease relapse with new bone metastases
- Platinum-free interval of 12 months
- GFR: 50 ml/min

Jun 2024

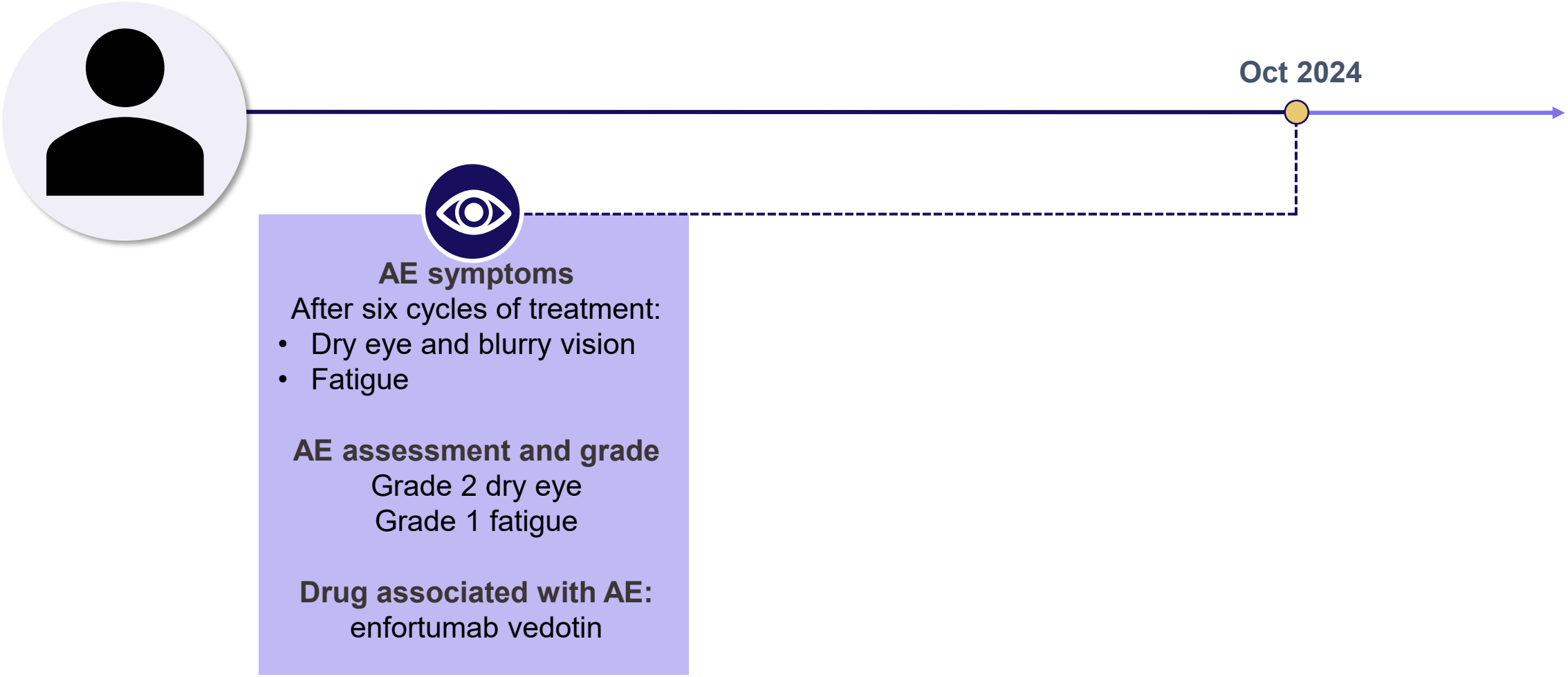
Treatment

- Started on **enfortumab vedotin** 1.25 mg/kg on Days 1, 8, and 15

Fictitious patient case study created for illustrative purposes.

GFR, glomerular filtration rate; N, node stage; p, pathological stage; UC, urothelial carcinoma; T, tumor stage; y, after neoadjuvant therapy.

AE presentation and management: Ocular toxicity



Fictitious patient case study created for illustrative purposes.

AE, adverse event; EV, enfortumab vedotin.

Question for the audience

How would you approach managing this adverse event?

- A. Referral to ophthalmologist
- B. Maintain EV dose and start use of artificial tears
- C. Permanently discontinue EV
- D. Other

EV, enfortumab vedotin.

Question for the audience

How would you approach managing this adverse event?

- **A** Referral to ophthalmologist
- **B** Maintain EV dose and start use of artificial tears[1]
- **C** Permanently discontinue EV
- **D** Other

EV, enfortumab vedotin.

1. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

AE presentation and management: Ocular toxicity

Oct 2024

AE symptoms

After six cycles of treatment:

- Dry eye and blurry vision
- Fatigue

AE assessment and grade

Grade 2 dry eye

Grade 1 fatigue

Drug associated with AE:

EV

Dosage

- Decided to continue EV at the same dose of 1.25 mg/kg

Management strategies

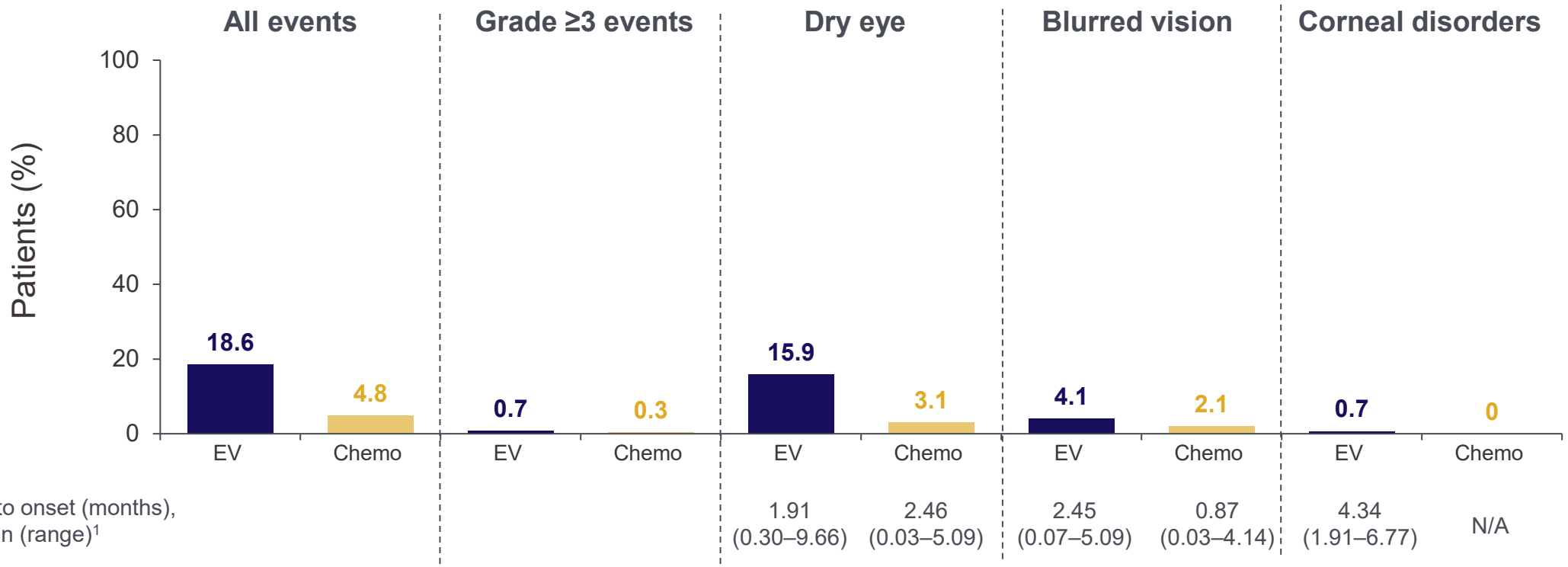
- Started artificial tears
- Referral to ophthalmologist
- Ophthalmologist evaluation showed Grade 1 keratitis without signs of uveitis or retinal pathology

Fictitious patient case study created for illustrative purposes.

AE, adverse event; EV, enfortumab vedotin.

In EV-301, ocular AEs were mostly mild to moderate in severity, with dry eye being the most common[1,2]

Incidence of treatment-related ocular AEs by type[1]*



Ocular toxicity also occurs with other ADCs and is considered to be due to on- and off-target delivery of cytotoxic payload to ocular tissues[3]

Median follow-up: 11.1 months. Analysis of the safety population (all patients who received any amount of study drug).[4]
*TRAEs are AEs for which there is a reasonable possibility that the event was caused by study treatment, according to the study investigator.[4]
ADC, antibody–drug conjugate; AE, adverse event; chemo, chemotherapy; EV, enfortumab vedotin; N/A, not applicable; TRAE, treatment-related adverse event.
1. Powles T et al. *N Engl J Med* 2021;384:1125–1135 (supplementary appendix); 2. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025; 3. Eaton JS et al. *J Ocul Pharmacol Ther* 2015;31:589–604;
4. Powles T et al. *N Engl J Med* 2021;384:1125–1135.

Risk factors for the development of ocular AEs

Risk factors for dry eye[1]

- Older age

Risk factors for keratitis[1]

- Contact lens use

Pre-existing ocular disorders are not a contraindication to EV[2]

Ocular AEs may be due to the **robust ocular vascular supply** leading to high delivery of cytotoxic MMAE, and **rapidly dividing** cell types within the eye[3,4]

AE, adverse event; EV, enfortumab vedotin; MMAE, monomethyl auristatin E.

1. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9; 2. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 3. Lucas R et al. *Antibodies* 2019;8:3; 4. Eaton JS et al. *J Ocul Pharmacol Ther* 2015;31:589–604.

Specialists can support monitoring and management of eye health[1,2]

Before initiation of EV (baseline)*

Be aware of risk factors including **pre-existing** ocular disease[1]

Routine monitoring

Monitor for ocular disorders[2]

Ensure the patient's eye care professional is aware of their EV therapy[1]

Management

Consider **artificial tears** for prophylaxis of dry eye[1,2]

Ophthalmological evaluation

Consider **referral** if ocular symptoms do not resolve or worsen[1,2]

*Baseline and routine eye examinations are not required for treatment with EV.[1]
EV, enfortumab vedotin.
1. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9; 2. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics.

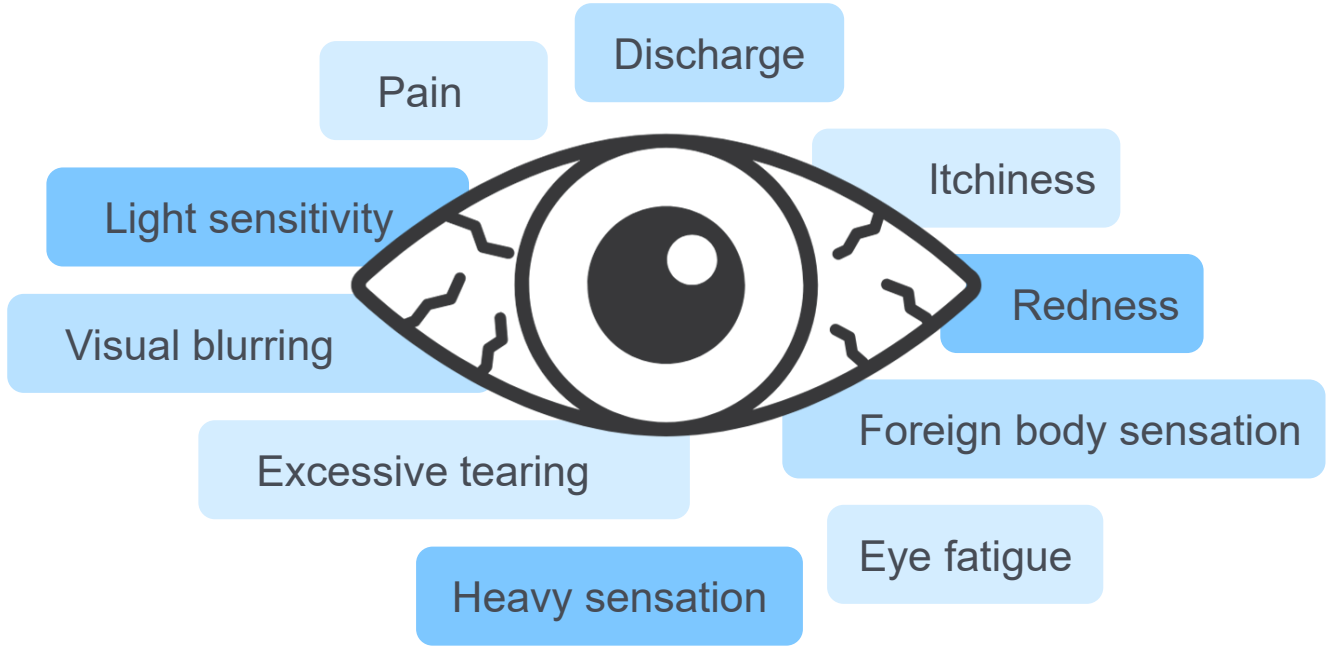
Dry eye is well characterized with clear signs and symptoms

Results in **insufficient lubrication to the tear film** leading to disruption of the ocular surface[1]

Commonly presents as intermittent or fluctuating **blurry vision**[1]

Can lead to ocular **discomfort**, visual **defects** and **blindness** if untreated[1]

Signs and symptoms of dry eye[1,2]



Patient education on the signs and symptoms of ocular AEs is vital for prompt identification and reducing the risk and severity of AEs[3]

AE, adverse event.

1. Verjee MA et al. *Ophthalmol Ther* 2020;9:877–888; 2. Tsubota K et al. *Int J Mol Sci* 2020;21:9271; 3. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9.

Symptoms and visual acuity are used to grade dry eye

	Grade 1	Grade 2	Grade 3
	**Asymptomatic**	**Symptomatic**	**Symptomatic**
	Clinical or diagnostic observations only	Moderate decrease in VA (BCVA 20/40 and better, or ≤3 lines decreased vision from known baseline)	Marked decrease in VA (BCVA worse than 20/40, or >3 lines decreased vision from known baseline, up to 20/200). Activities of daily living involving self-care are limited
	Symptoms relieved by lubricants		

BCVA, best corrected visual acuity; VA, visual acuity.

US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025.

Summary

Ocular AEs with EV are mostly mild to moderate and usually consist of dry eye and blurry vision.[1,2] Considering risk factors (use of contact lenses) and taking prophylactic measures (use of artificial tears) can help to reduce the risk of developing ocular AEs[3,4]

Guidance is available in the SmPC to support patients in achieving optimal treatment outcomes through appropriate management of ocular AEs with EV[3,4]

Effective communication between patients, HCPs, and specialists should play an active role in the management of AEs to ensure timely identification and effective care[5]

EV is an effective treatment option for a broad patient population including those with comorbidities and difficult-to-treat cases. Effective management strategies can be utilised to manage AEs, to ensure that patients receive optimal treatment outcomes[4]

AE, adverse event; EV, enfortumab vedotin; HCP, healthcare professional; SmPC, Summary of Product Characteristics.

1. Powles T et al. *N Engl J Med* 2021;384:1125–1135 (supplementary appendix); 2. US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Available at: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf. Last accessed: June 2025; 3. Pace A et al. *Clin J Oncol Nurs* 2021;25:E1–E9;
4. PADCEV™ (enfortumab vedotin). Summary of Product Characteristics; 5. Brower B et al. *Front Oncol* 2024;14:1326715.

Genitourinary Masterclass

astellas

Please refer to the Korean PI for PADCEV® (enfortumab vedotin) via the following link or QR Code:

<PADCEV 20mg>

<PADCEV 30mg>

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PI, Prescribing Information