

## Regimen Monograph

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## A - Regimen Name

# ENFO Regimen

Enfortumab vedotin

**Disease Site**      Genitourinary  
Bladder / Urothelial

**Intent**              Palliative

**Regimen Category**      **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses**      For the treatment of locally advanced unresectable or metastatic urothelial cancer, in patients who have previously received platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor, and have good performance status

**Supplementary Public Funding**      [enfortumab vedotin](#)  
New Drug Funding Program (Enfortumab Vedotin - Previously Treated Advanced or Metastatic Urothelial Cancer) ([NDFP Website](#))

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**B - Drug Regimen**

[enfortumab vedotin](#)\* 1.25 mg /kg IV Days 1, 8, 15

Subsequent doses should NOT be administered less than 1 week apart.

\*Dose is capped at a weight of 100 kg.

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**C - Cycle Frequency****REPEAT EVERY 28 DAYS**

Until disease progression or unacceptable toxicity

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**D - Premedication and Supportive Measures**

**Antiemetic Regimen:** Low

- Also refer to [CCO Antiemetic Recommendations](#).

**Screen for hepatitis B virus in all cancer patients starting systemic treatment.** Refer to the [hepatitis B virus screening and management](#) guideline.

**Premedication (Prophylaxis for Infusion Reactions):**

- Routine premedication is not recommended. No premedication was given for the first dose of enfortumab vedotin during clinical trials.
- Patients who experience an infusion reaction may be premedicated for subsequent infusions. Premedication may include acetaminophen, an antihistamine (e.g., diphenhydramine hydrochloride), and a corticosteroid given 30–60 minutes prior to each infusion. (Powles 2021)

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**E - Dose Modifications**

Doses should be modified according to the protocol by which the patient is being treated.

**Dosage with toxicity**

<b>Dose Level</b>	<b>Enfortumab Vedotin Dose (mg/kg)*</b>
0	1.25
-1	1
-2	0.75
-3	0.5
-4	Discontinue

\*For patients  $\leq 100$  kg. If weight is  $> 100$  kg, dose should be based on 100 kg.

<b>Toxicity</b>	<b>Grade/Severity</b>	<b>Action</b>
Skin Reactions	Grade 1 or 2	Consider topical corticosteroids and antihistamines as needed.
	Grade 3, worsening reactions, or suspected SJS or TEN	Hold*. Consider dermatological referral. Resume at same dose or consider 1 dose level ↓.
	Grade 4, recurrent Grade 3, or confirmed SJS or TEN	Discontinue.
Hyperglycemia	Blood glucose $> 13.9$ mmol/L	Hold*. Resume at same dose.
Pneumonitis	Grade 2	Hold*. Resume at the same dose or consider 1 dose level ↓.
	Grade 3 or 4	Discontinue.
Peripheral Neuropathy	Grade 2	Hold*.  1st occurrence: resume at same dose. Recurrence: resume at 1 dose level ↓.
	Grade 3 or 4	Discontinue.

Ocular Toxicity	Any	Consider holding or reducing dose.  Consider ophthalmology referral if symptoms do not resolve or worsen.
Other Non-hematologic Toxicity	Grade 3	Hold*. Resume at same dose or consider 1 dose level ↓.
	Grade 4	Discontinue.
Hematologic Toxicity	Grade 2 thrombocytopenia	Hold*. Resume at same dose or consider 1 dose level ↓.
	Grade 3	
	Grade 4	Hold*. Resume at 1 dose level ↓ or discontinue.

\*Do not restart treatment until blood glucose resolved to  $\leq 13.9$  mmol/L, and other toxicities  $\leq$  Grade 1.

### **Hepatic Impairment**

MMAE exposure is likely increased in patients with moderate or severe hepatic impairment.

<b>Hepatic Impairment</b>	<b>Enfortumab Vedotin Dose</b>
Child-Pugh A	No adjustment required.
Child-Pugh B	Not studied; avoid use.
Child-Pugh C	

### **Renal Impairment**

No dosage adjustment is required with renal impairment. The effect of end stage renal disease with or without dialysis on the pharmacokinetics of ADC or unconjugated MMAE is unknown.

### **Dosage in the Elderly**

No dose adjustment is required in patients  $\geq 65$  years of age. No overall differences in efficacy were observed between patients  $\geq 65$  years and those  $< 65$  years. Patients  $\geq 65$  years were more likely to experience serious adverse events or treatment discontinuation.

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Refer to [enfortumab vedotin](#) drug monograph(s) for additional details of adverse effects.

<b>Very common (≥ 50%)</b>	<b>Common (25-49%)</b>	<b>Less common (10-24%)</b>	<b>Uncommon (&lt; 10%), but may be severe or life-threatening</b>
<ul style="list-style-type: none"><li>• Rash (may be severe)</li><li>• Fatigue</li><li>• Peripheral neuropathy (may be severe)</li></ul>	<ul style="list-style-type: none"><li>• Alopecia</li><li>• Anorexia, weight loss</li><li>• Diarrhea</li><li>• Nausea, vomiting</li><li>• Constipation</li><li>• Dysgeusia</li><li>• Musculoskeletal pain</li></ul>	<ul style="list-style-type: none"><li>• Dry eye (may be severe)</li><li>• Abdominal pain</li><li>• ↑ LFTs</li><li>• Myelosuppression ± infection, bleeding (may be severe)</li><li>• Hyperglycemia (may be severe)</li><li>• Insomnia</li></ul>	<ul style="list-style-type: none"><li>• Tachycardia</li><li>• Pneumonitis</li><li>• Extravasation</li><li>• Epidermal necrosis</li><li>• Stevens-Johnson syndrome</li><li>• Toxic epidermal necrolysis</li><li>• Hand-foot syndrome</li><li>• Ocular disorders</li></ul>

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Refer to [enfortumab vedotin](#) drug monograph(s) for additional details.

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## H - Drug Administration and Special Precautions

Refer to [enfortumab vedotin](#) drug monograph(s) for additional details.

### Administration

- Reconstitute each vial with Sterile Water for Injection. Swirl gently; do not shake the solution.
- Dilute in D5W, NS, or Ringer's lactate. Invert infusion bag gently to mix.
- Final concentration should be 0.3 mg/mL to 4 mg/mL.
- Administer as an IV infusion over 30 minutes. Do NOT administer as an IV push or bolus.
- Do NOT administer other drugs through the same IV line.
- If extravasation occurs during administration, stop the infusion and monitor for adverse reactions (e.g., skin and soft tissue injury).
- Do not expose the vials or diluted drug to direct sunlight.
- Store unopened vials in a refrigerator at 2-8°C. Do not freeze.

### Contraindications/Precautions

- Patients who have a hypersensitivity to this drug or any of its components

### Warning/Precautions

- Do NOT start enfortumab vedotin in patients with pre-existing grade  $\geq 2$  neuropathy, ongoing clinically significant toxicity from previous treatment, active CNS metastases, uncontrolled diabetes, active keratitis or corneal ulcerations.

### Pregnancy/Lactation

- This regimen is not recommended for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is not recommended during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Probable

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Refer to the [hepatitis B virus screening and management](#) guideline for monitoring during and after treatment.

Recommended Clinical Monitoring

- CBC; Baseline, before each dose, and as clinically indicated
- Liver function tests; Baseline, before each dose, and as clinically indicated
- Blood glucose; Baseline and as clinically indicated (more frequently in patients with or at risk for diabetes mellitus or hyperglycemia)
- Clinical toxicity assessment for infection, bleeding, extravasation, peripheral neuropathy, GI, ocular, respiratory and skin effects; At each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

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J - Administrative Information

Approximate Patient Visit	0.5 to 1 hour
Pharmacy Workload (average time per visit)	23.407 minutes
Nursing Workload (average time per visit)	41.667 minutes

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## K - References

CADTH Reimbursement Recommendation: Enfortumab Vedotin (Padcev). Canadian Journal of Health Technologies. January 2022.

Enfortumab vedotin drug monograph. Ontario Health (Cancer Care Ontario).

Powles T, Rosenberg JE, Sonpavde GP, et al. Enfortumab vedotin in previously treated advanced urothelial carcinoma. N Engl J Med 2021;384(12):1125-35. doi: 10.1056/NEJMoa2035807.

**January 2025 Updated Dosage in the elderly section**

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## M - Disclaimer

### Regimen Abstracts

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

*Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.*

### Regimen Monographs

Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.

*The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended*



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*that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

*Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.*

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