**Regimen Monograph**

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

## A - Regimen Name

# ENFO+PEMB Regimen

**Enfortumab vedotin-Pembrolizumab**

**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.

This **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). 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.

**Rationale and Uses**

Treatment for patients with previously untreated locally advanced or metastatic urothelial carcinoma

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## B - Drug Regimen

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|---|---|---|---|
| enfortumab vedotin*† | 1.25 mg /kg | IV | Days 1 and 8 |

**(This drug is not publicly funded. Universal compassionate access program is available. )**

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

*Dose is capped at a weight of 100 kg.

| | | | |
|---|---|---|---|
| pembrolizumab† | 200 mg | IV | Day 1 |

**(This drug is not currently publicly funded for this regimen and intent)**

† Administer enfortumab vedotin before pembrolizumab when given on the same day. Provide for an interval of 30 minutes between the 2 drug infusions (for at least Cycle 1, Day 1). If well-tolerated, this interval can subsequently be reduced to 15 minutes.

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## C - Cycle Frequency

**REPEAT EVERY 21 DAYS**

Until disease progression or unacceptable toxicity (up to 35 cycles of pembrolizumab)

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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.

**Enfortumab Vedotin 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)

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

- Routine pre-medication is not recommended.
- May consider antipyretic and H1-receptor antagonist in patients who experienced a grade 1-2 infusion reaction.

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## J - Administrative Information

| | |
|---|---|
| Approximate Patient Visit | 1.5 hours |
| Pharmacy Workload (average time per visit) | 23.407 minutes |
| Nursing Workload (average time per visit) | 41.667 minutes |

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## K - References

Powles T, Valderrama BP, Gupta S, et al. Enfortumab vedotin and pembrolizumab in untreated advanced urothelial cancer. N Engl J Med 2024 Mar 7;390(10):875-88.

Product monograph: Enfortumab vedotin (Padcev). Seagen Inc., Aug 20, 2024.

**October 2024** new ST-QBP regimen

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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*

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***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.*

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