Regimen Monograph

A - Regimen Name

ENFO+PEMB Regimen

Enfortumab vedotin-Pembrolizumab

Disease Site

Genitourinary
Bladder / Urothelial

Intent

Neoadjuvant
Adjuvant

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

Perioperative treatment of muscle invasive bladder cancer (MIBC), in patients who are ineligible for cisplatin-containing chemotherapy

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B - Drug Regimen

enfortumab vedotin†	1.25 mg /kg	IV (max 125 mg)	Days 1 and 8

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

At least 7 days must have elapsed between enfortumab vedotin doses.

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

For 3 pre-operative and 6 post-operative cycles

Then, continue with pembrolizumab monotherapy (PEMB) after completion of post-operative ENFO+PEMB, unless 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.

Enfortumab Vedotin Premedication (Prophylaxis for Infusion Reactions):

- Routine premedication is not recommended.
- 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.

Other Supportive Care:

- Avoid the use of corticosteroids or immunosuppressants before starting pembrolizumab treatment.

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J - Administrative Information

Approximate Patient Visit	1.5 hours

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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.

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

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

Vulsteke C, Adra N, Danchaivijitr P, Sabadash M, et al. Perioperative enfortumab vedotin and pembrolizumab in bladder cancer. N Engl J Med 2026 Feb 18. doi: 10.1056/NEJMoa2511674.

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M - Disclaimer

Regimen Abstracts

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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.

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