Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

LENV+PEMB Regimen

Lenvatinib-Pembrolizumab

Disease Site

Genitourinary
Renal Cell / Kidney

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

For the treatment of advanced or metastatic renal cell carcinoma (RCC) in patients who have not received prior systemic therapy for advanced disease, are not candidates for curative surgery or radiation, and have a good performance status.

Supplementary

lenvatinib

Public Funding	Exceptional Access Program (lenvatinib - In Combination with Pembrolizumab for First-Line Advanced or Metastatic Renal Cell Carcinoma) (EAP Website) **pembrolizumab** New Drug Funding Program (Pembrolizumab - In Combination with Lenvatinib for First-Line Advanced or Metastatic Renal Cell Carcinoma)

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B - Drug Regimen

lenvatinib	20 mg	PO	Daily
AND			
pembrolizumab[1]	2 mg /kg	IV (max 200 mg)	Day 1, every 3 weeks
OR			
pembrolizumab[1]	4 mg /kg	IV (max 400 mg)	Day 1, every 6 weeks

[1]Dosing based on NDFP funding criteria.

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C - Cycle Frequency

Lenvatinib: Continuous treatment, until disease progression or unacceptable toxicity

Use the regimen code LENV(MNT) for single agent lenvatinib after completion of pembrolizumab treatment.

Pembrolizumab:

2 mg /kg dosing: REPEAT **EVERY 3 WEEKS**

4 mg /kg dosing: REPEAT **EVERY 6 WEEKS**

Continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

Refer to NDFP form for details on pembrolizumab retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal; consider prophylaxis daily for lenvatinib

- 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.

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 treatment.

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J - Administrative Information

Approximate Patient Visit	0.75 hour
Pharmacy Workload (average time per visit)	19.75 minutes minutes
Nursing Workload (average time per visit)	40.75 minutes minutes

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K - References

CADTH Reimbursement Recommendation: Lenvatinib (Lenvima) in Combination With Pembrolizumab (Keytruda) - for advanced or metastatic renal cell carcinoma. Canadian Journal of Health Technologies. July 2022.

Motzer R, Alekseev B, Rha S-Y, et al. Lenvatinib plus pembrolizumab or everolimus for advanced renal cell carcinoma. N Engl J Med 2021;384:1289-300.

August 2023 New ST-QBP regimen

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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.

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 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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