Regimen Monograph

A - Regimen Name

AXIT+PEMB Regimen

Axitinib-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

First-line treatment of advanced or metastatic renal cell carcinoma in patients who have good performance status

Supplementary Public Funding	**aXitinib** Exceptional Access Program (aXitinib - In combination with pembrolizumab for first-line advanced or metastatic renal cell carcinoma) (EAP Website) **pembrolizumab** New Drug Funding Program (Pembrolizumab - In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell Carcinoma) (NDFP Website)

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B - Drug Regimen

aXitinib[1]	5 mg	PO	BID

[1]the dose can be increased to 7 mg, then 10 mg BID if tolerated.

And Pembrolizumab:

pembrolizumab[2]	2 mg /kg	IV (max 200mg)	Day 1, Q21 days

OR

pembrolizumab[2]	4 mg /kg	IV (max 400mg)	Day 1, Q42 days

[2]Dosing based on NDFP funding criteria

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C - Cycle Frequency

aXitinib: **CONTINUOUS TREATMENT** until disease progression or unacceptable toxicity

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

pembrolizumab:

2 mg/kg dosing: **REPEAT EVERY 21 DAYS**

4 mg /kg dosing: **REPEAT EVERY 42 DAYS**

Until disease progression or unacceptable toxicity up to a maximum of 2 years (35 doses given q3 weeks or 18 doses given q6 weeks), whichever occurs first.

Refer to NDFP form for details on pembrolizumab retreatment.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal – No routine prophylaxis; PRN recommended

Other Supportive Care:

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.

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J - Administrative Information

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

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K - References

Rini BI, Plimack ER, Stus V, et al. Pembrolizumab plus axitinib versus sunitinib for advanced renal-cell carcinoma. N Engl J Med; February 16, 2019. DOI: 10.1056/NEJMoa1816714

August 2023 Modified cycle frequency section

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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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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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