**Regimen Monograph**

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

## A - Regimen Name

# CABO+NIVL Regimen

**Cabozantinib-Nivolumab**

# CABO(MNT) Regimen

**Cabozantinib (maintenance)**

| | |
|---|---|
| **Disease Site** | Genitourinary<br>Renal Cell / Kidney |
| **Intent** | Palliative |
| **Regimen Category** | **Evidence-informed :**<br><br>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.<br><br>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 advanced or metastatic renal cell carcinoma (RCC), who have not received prior systemic therapy for advanced disease. |

Patients must have good performance status and disease that is not amenable to curative surgery or radiation.

**Supplementary Public Funding**

**cabozantinib (tablet)**
Exceptional Access Program (cabozantinib – For the first-line treatment of adult patients with advanced or metastatic renal cell carcinoma, in combination with nivolumab, according to clinical criteria) (EAP Website)

**nivolumab**
New Drug Funding Program (Nivolumab - In Combination with Cabozantinib for First Line Advanced or Metastatic Renal Cell Carcinoma) (NDFP Website )

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## B - Drug Regimen

| | | | |
|---|---|---|---|
| **nivolumab** | 3 mg /kg | IV (max 240 mg)* | Day 1, every 2 weeks |

**OR**

| | | | |
|---|---|---|---|
| **nivolumab** | 6 mg /kg | IV (max 480 mg)* | Day 1, every 4 weeks |

* Dosing based on NDFP funding criteria

**With Cabozantinib:**

| | | | |
|---|---|---|---|
| **cabozantinib (tablet)** | 40 mg | PO | Daily |

(On nivolumab treatment days, nivolumab should be administered first then cabozantinib (on an empty stomach) in the evening.)

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## C - Cycle Frequency

**Cabozantinib:** Continuous treatment unless disease progression or unacceptable toxicity

Use the regimen code CABO(MNT) for single agent cabozantinib after completion of nivolumab treatment.

**Nivolumab:**

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

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

Continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (52 doses given q2 weeks or 26 doses given every 4 weeks), whichever occurs first.

Patients who experience unacceptable toxicity to either nivolumab or cabozantinib may continue treatment with the other agent until disease progression (up to a maximum of 2 years for nivolumab).

Refer to NDFP form for details on nivolumab retreatment.

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:**

- Cabozantinib: Moderate – Consider prophylaxis daily
- Nivolumab: Minimal
- 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.

**Nivolumab pre-medications (prophylaxis for infusion reaction):**

- Routine pre-medication is not recommended.
- May consider pre-medication with antipyretics and H1-receptor antagonists if an IR has occurred in the past.

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## J - Administrative Information

Cabozantinib: Outpatient prescription for home administration

**Approximate Patient Visit**
**CABO+NIVL** Nivolumab: 1 hour

**Pharmacy Workload** **(average time per visit)**
**CABO+NIVL** 18.7 minutes

**Nursing Workload** **(average time per visit)**
**CABO+NIVL** 40.75 minutes

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## K - References

Cabozantinib drug monograph, Ontario Health (Cancer Care Ontario).

CADTH reimbursement recommendation: Cabozantinib (first-line treatment of adult patients with advanced (not amenable to curative surgery or radiation therapy) or metastatic renal cell carcinoma). November 2023.

CADTH reimbursement review: Cabozantinib (advanced or metastatic renal cell carcinoma). February 2024.

Choueiri TK, Powles T, Burotto M, et al. Nivolumab plus cabozantinib versus sunitinib for advanced renal-cell carcinoma. N Engl J Med 2021 Mar 4;384(9):829-41.

Nivolumab drug monograph, Ontario Health (Cancer Care Ontario).

**November 2024** Added CABO(MNT) regimen code

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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.*

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