#### Regimen Monograph

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

## A - Regimen Name

# CISPGEMC+NIVL+IPIL Regimen

CISplatin-Gemcitabine-Nivolumab-Ipilimumab

Disease Site Lung

Non-Small Cell

**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 metastatic or recurrent non-small cell lung cancer (NSCLC), with no known epidermal growth factor (EGFR) or anasplatic lymphoma kinase (ALK) genomic tumour aberrations, in patients with good performance status

# Supplementary Public Funding

# <u>nivolumab</u>

New Drug Funding Program (Nivolumab plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent Non-Small Cell Lung Cancer) (NDFP Website)

# <u>ipilimumab</u>

New Drug Funding Program (Nivolumab plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent Non-Small Cell Lung Cancer) (NDFP Website)

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| B - Drug Regimen                              |                  |    |           |
|-----------------------------------------------|------------------|----|-----------|
| Cycle 1:                                      |                  |    |           |
| nivolumab*                                    | 4.5 mg /kg       | IV | Day 1     |
| * NDFP funded dosing; maximum 360 mg per dose |                  |    |           |
| <u>ipilimumab</u>                             | 1 mg /kg         | IV | Day 1     |
| <u>gemcitabine</u>                            | 1000-1250 mg /m² | IV | Days 1, 8 |
| <u>CISplatin</u>                              | 75 mg /m²        | IV | Day 1     |
|                                               |                  |    |           |
| Cycle 2:                                      |                  |    |           |
| nivolumab*                                    | 4.5 mg /kg       | IV | Day 1     |
| * maximum 360 mg per dose                     |                  |    |           |
| <u>gemcitabine</u>                            | 1000-1250 mg /m² | IV | Days 1, 8 |
| <u>CISplatin</u>                              | 75 mg /m²        | IV | Day 1     |
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# C - Cycle Frequency

Give every 21 days for 2 cycles only, unless disease progression or unacceptable toxicity occurs.

After completion of cycles 1 and 2, continue with nivolumab q3 weeks and ipilimumab q6 weeks [see NIVL+IPIL(MNT) for details].

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# **D** - Premedication and Supportive Measures

# Pre-medications (prophylaxis for infusion reaction):

#### **Nivolumab:**

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

## Ipilimumab:

- Consider an antipyretic and H1-receptor antagonist
- For ipilimumab-related drug fever, premedicate with acetaminophen for subsequent doses and may repeat the antipyretic at 6-12 hours after the ipilimumab infusion.

#### **Antiemetic Regimen:**

- High (Day 1)
- Low (Day 8)

Also refer to CCO Antiemetic Recommendations.

# **Other Supportive Care:**

**Cisplatin:** All patients should receive adequate hydration and premedication for emesis, according to local guidelines.

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#### J - Administrative Information

Approximate Patient Visit 5 hours

Pharmacy Workload (average time per visit) 43.685 minutes

Nursing Workload (average time per visit) 49.917 minutes

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#### K - References

CISPGEMC regimen monograph (Lung-NSCLC palliative). Ontario Health (Cancer Care Ontario).

Paz-Ares L, Ciuleanu TE, Cobo M, et al. First-line nivolumab plus ipilimumab combined with two cycles of chemotherapy in patients with non-small-cell lung cancer (CheckMate 9LA): an international, randomised, open-label, phase 3 trial. Lancet Oncol . 2021 Feb;22(2):198-211. doi: 10.1016/S1470-2045(20)30641-0.

pCODR expert review committee final recommendation: Nivolumab (Opdivo) in combination with ipilimumab (Yervoy) and two cycles of platinum-based chemotherapy, March 4, 2021.

August 2022 Added nursing and pharmacy workload

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#### M - Disclaimer

#### Regimen Abstracts

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# Regimen Monographs

Refer to the <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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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