Regimen Monograph

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

A - Regimen Name

CRBPGEMC+NIVL+IPIL Regimen

CARBOplatin-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>CARBOplatin</u>	AUC 5	IV	Day 1
Cycle 2:			
<u>nivolumab</u>	4.5 mg /kg	IV	Day 1
* maximum 360 mg per dose			
gemcitabine	1000-1250 mg /m²	IV	Days 1, 8
<u>CARBOplatin</u>	AUC 5	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:

- Day 1: Moderate + NK1 antagonist (Carboplatin AUC ≥ 5)
- Day 8: Low

Also refer to CCO Antiemetic Recommendations.

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J - Administrative Information

Approximate Patient Visit 3 hours

Pharmacy Workload (average time per visit) 36.751 minutes

Nursing Workload (average time per visit) 47.083 minutes

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K - References

CRBPGEMC 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 pharmacy and nursing workload

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M - Disclaimer

Regimen Abstracts

A 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). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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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.

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