Regimen Monograph

 Regimen Name
 Drug Regimen
 Cycle Frequency
 Premedication and Supportive Measures
 Administrative Information

 References
 Other Notes
 Disclaimer

A - Regimen Name

CISPPEME+NIVL+IPIL Regimen

CISplatin-Pemetrexed-Nivolumab-Ipilimumab

Disease Site Lung Non-Small Cell

Intent Palliative

Regimen Evidence-informed :

Category

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 andFirst-line treatment of metastatic or recurrent non-squamous 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

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Supplementary Public Funding	nivolumabNew 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)ipilimumabNew Drug Funding Program (Nivolumab plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent Non- 			
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B - Drug Regimen				
Cycle 1:				
nivolumab*	4.5 mg /k	kg IV	Day 1	
* NDFP funded dosing; maximum 360 mg per dose				
<u>ipilimumab</u>	1 mg /kg	IV	Day 1	
pemetrexed	500 mg /	m² IV	Day 1	
CISplatin	75 mg /m	ı² Ⅳ	Day 1	
Cycle 2:				
<u>nivolumab</u> *	4.5 mg /k	kg IV	Day 1	
*maximum 360 mg per dose				
pemetrexed	500 mg /	m² IV	Day 1	
<u>CISplatin</u>	75 mg /m	n² 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

Also refer to <u>CCO Antiemetic Recommendations</u>.

Other Supportive Care:

Pemetrexed:

- Vitamin B12 1000mcg IM every 9 weeks, Folic acid 0.4 1 mg PO daily (both starting ≥ 1 week prior to pemetrexed administration; continue throughout and 3 weeks after last dose of Pemetrexed).
- Dexamethasone 4mg PO BID for 3 days starting day before chemotherapy suggested for rash prophylaxis.
- Note: NSAIDs should be held for 2-5 days prior and 2 days after pemetrexed (refer to pemetrexed monograph)

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

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J - Administrative Information

Approximate Patient Visit4 to 5 hoursPharmacy Workload (average time per visit)43.685 minutesNursing Workload (average time per visit)64.833 minutes

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K - References

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 in combination with ipilimumab and two cycles of platinum-based chemotherapy, March 2021.

September 2023 Updated the "Administrative Information" section with pharmacy and nursing workload.

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M - Disclaimer

Regimen Abstracts

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Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not

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undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

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.

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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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