Regimen Monograph

A - Regimen Name

GEFI Regimen

Gefitinib

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.
Rationale and Uses	First-line treatment of patients with locally advanced (incurable) or metastatic non-small cell lung cancer, who have known activating mutations of the EGFR tyrosine kinase.
Supplementary Public Funding	**gefitinib** Exceptional Access Program (gefitinib - First-line monotherapy in locally advanced (not amenable to curative therapy) or metastatic NSCLC patients who have activating mutations of EGFR-TK, with specific criteria) (EAP Website)

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B - Drug Regimen

gefitinib	250 mg	PO	Daily

(Outpatient prescription available in 250mg tablets)

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C - Cycle Frequency

CONTINUOUS TREATMENT

Until disease progression or unacceptable toxicity

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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.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

Dosage with toxicity

Toxicity	Action
Grade 2 skin, eye toxicity, poorly tolerated diarrhea	Hold*, restart at 250mg daily when recovered
Grade 3 skin, eye toxicity, diarrhea, LFTs, dehydration	Hold*, may restart at 250mg daily when recovered
Grade 4 toxicities OR GI perforation OR	Discontinue

treatment intolerance despite dose interruption	
Keratitis	Hold and investigate. Consider discontinuing if ulcerative.
Pneumonitis/ILD	Hold in the presence of cough/dyspnea/fever and investigate. Discontinue if pneumonitis confirmed.

* up to 14 days for diarrhea and skin toxicity

Hepatic Impairment

Increased gefitinib exposure has been reported in patients with moderate and severe hepatic impairment due to cirrhosis. Dose adjustment is not required, but use with caution and monitor closely. Exercise caution in patients with mild to moderate changes in liver function; consider discontinuing gefitinib with severe changes in liver function.

Renal Impairment

No adjustment required in mild or moderate renal impairment. No specific recommendations were found for patients with severe renal impairment.

Dosage in the Elderly

No dosage adjustment required.

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F - Adverse Effects

Refer to gefitinib drug monograph(s) for additional details of adverse effects

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Rash (may	• Diarrhea (may	• Anorexia	• Hypersensitivity

be severe)	be severe)	• Nausea, vomiting • Insomnia • Fatigue • Paronychia • Mucositis • Increased LFTs (may be severe) • Alopecia	• Hemorrhage • GI perforation • ILD/pneumonitis • Arterial thromboembolism • Pancreatitis • Increased creatinine • Cutaneous vasculitis • Keratitis

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G - Interactions

Refer to gefitinib drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to gefitinib drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Close monitoring of INR in patients on warfarin, especially initially, or when gefitinib is held or discontinued
- Electrolytes, creatinine and urea, especially in patients at high risk of dehydration; baseline and periodic
- Liver function tests; baseline and routine
- Clinical assessments and grading of GI, skin, eye and respiratory symptoms; at each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Gefitinib drug monograph, Cancer Care Ontario.

Mok TS, Wu YL, Thongprasert S, et al. Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. N Engl J Med 2009; 361(10): 947-57.

Fukuoka M, Wu YL, Thongprasert S, et al. Biomarker analyses and final overall survival results from a phase III, randomized, open-label, first-line study of gefitinib versus carboplatin/paclitaxel in clinically selected patients with advanced non-small-cell lung cancer in Asia (IPASS). Clin Oncol 2011;29(21):2866-74.

PEBC Advice Documents or Guidelines

- Use of the EGFR Inhibitors Gefitinib, Erlotinib, Afatinib, Dacomitinib or Icotinib in the Treatment of NSCLC
- Systemic Treatment for Patients with Advanced Non-Small Cell Lung Cancer
- Therapy for Stage IV Non–Small-Cell Lung Cancer With Driver Alterations: ASCO and OH(CCO) Joint Guideline Update

March 2021 Added PEBC guideline link

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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

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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.

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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