Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

ERLO Regimen

Erlotinib

Disease Site
Gynecologic
Vulva

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
For the treatment of locally advanced, primary, recurrent or metastatic squamous cell carcinoma of the vulva. Based on a single arm phase II trial of 41 patients with a response rate of 28%.

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B - Drug Regimen

erlotinib	150 mg	PO	Daily

(This drug is not currently publicly funded for this regimen and intent)

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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:

Provide patient with loperamide (including instructions) for diarrhea management.

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

Dose levels: 150 mg, 100 mg, 50 mg

Toxicity	Severity	Action
Skin rash	Grade 2 or 3	If tolerable, continue at the same dose and treat symptoms. If intolerable, hold* and reduce 1 dose level. Consider dose re-escaltion as tolerated.
Diarrhea	Grade 1 or tolerable Grade 2	Continue at the same dose and manage with loperamide
	Grade 2 x 48-72 h despite optimal medical management	Manage with loperamide and reduce 1 dose level. Do not re-escalate reduce dose.
	Grade 3	Manage with loperamide, hold* and reduce 1 dose level. Do not re-escalate reduced dose.
	Grade 4	Discontinue
LFTs	Grade 3	Reduce 1 dose level
	Grade 4	Discontinue
Patients with dehydration at risk of renal failure; Acute/new or worsening ocular disorders	n/a	Hold* or Discontinue
Acute/new or worsening pulmonary symptoms (e.g. dyspnea, cough, fever)	n/a	Hold*; investigate and treat appropriately. Discontinue if interstitial lung disease confirmed.
Other toxicity	Grade 3	Reduce by one dose level especially if being administered with potent CYP3A4 inhibitors
• GI bleeding/perforation • Severe bullous, blistering or exfoliating rashes • Rhabdomyolysis • Other grade 4 toxicity	n/a	Discontinue; treat patient appropriately

*Hold until ≤ grade 1 for a maximum of 14 days; if further hold required, discontinue

Hepatic Impairment

Use with caution in combination with other hepatotoxic drugs. See table above for hepatic toxicity during treatment.

Hepatic Impairment	Bilirubin		Transaminases	Erlotinib dose
Mild	< 1.5 x ULN	and	1 - 2.5 x ULN	100%, caution
Moderate	1.5 - 3 x ULN	and/or	2.5 - 5 x ULN	Caution; consider starting at reduced dose. If worsens, hold then 50% or discontinue
Severe	> 3 x ULN (or 2 x baseline values)	or	> 5 x ULN (or 3 x baseline values)	Do not treat

Renal Impairment

Not significantly renally excreted. No dose adjustment required.

Dosage in the Elderly

No adjustment required.

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F - Adverse Effects

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

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Rash (may be severe) • Diarrhea (may be severe) • Anorexia • Fatigue • Cough, dyspnea (may be severe) • Nausea, vomiting • Mucositis • Paronychia • Conjunctivitis (may be severe, including ulceration) • Abdominal pain	• ↑ LFTs • Rhabdomyolysis • Venous thromboembolism • GI perforation, bleed • Nephrotoxicity • Photosensitivity • Hemolysis

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G - Interactions

Refer to erlotinib drug monograph(s) for additional details

- Avoid use with potent CYP3A4 inducers (e.g. rifampin, phenytoin, St. John's wort) and inhibtiors (e.g. diltiazem, erythromycin, Grapefruit juice)
- If must co-administer with potent CYP3A4 inhibitor, consider erlotinib dose reduction
- Avoid concomittant use with drugs that increase gastric pH (e.g. proton pump inhibitors, H2-antagonists). If must co-administer, take erlotinib 2 hours prior to or 10 hours following acid reducers.
- Cigarette smoking increases erlotinib clearance and may reduce efficacy. Encourage smoking cessation.
- Caution and monitor closely in patients receiving oral anticoagulants and statin medications given increased risk of bleeding and rhabdomyolysis, respectively.

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H - Drug Administration and Special Precautions

Refer to erlotinib drug monograph(s) for additional details

Administration:

- Administer on an empty stomach, 1 hour before or 2 hours after a meal.
- Avoid grapefruit, starfruit, Seville oranges, their juices or products during erlotinib treatment.

Contraindications:

- Patients who have a hypersensitivity to this drug or any of its components

Warnings/precautions:

- Erlotinib has not been studied in patients with severe hepatic or renal impairment.
- Patients on oral anticoagulants should be closely monitored when doses of erlotinib are started, modified or discontinued.
- Contains lactose; carefully consider use in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption

Pregnancy/Lactation:

- Erlotinib is not recommended for use in pregnancy. Adequate contraception should be used by both sexes during treatment, and for at least **2 weeks** after the last dose.
- Breastfeeding is not recommended during treatment and for at least **2 weeks** after the last dose.
- Fertility effects: Unlikely

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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

- Liver function tests; Baseline and at each visit, more frequent if abnormal.
- Renal function tests, including electrolytes; Baseline and at each visit
- INR, in patients on warfarin; Baseline and when dose modified, held, or discontinued.
- Clinical toxicity assessment of diarrhea, skin/nails, stomatitis, thromboembolism, infection, bleeding, ocular and respiratory effects; 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

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

Horowitz NS, Olawaiye AB, Borger DR, et al. Phase II trial of erlotinib in women with squamous cell carcinoma of the vulva. Gynecol Oncol. 2012 Oct;127(1):141-6.

October 2022 Modified Pregnancy/lactation section

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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.

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.

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