Regimen Monograph

A - Regimen Name

BICALPRL Regimen

Bicalutamide-Leuprolide

Disease Site

Genitourinary
Prostate

Intent

Neoadjuvant
Adjuvant
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 cytoreduction before brachytherapy
- in combination with radiotherapy for the treatment of high-risk localized prostate cancer
- for palliative treatment of recurrent, progressive or metastatic prostate cancer

Supplementary Public Funding	**leuprolide** ODB - General Benefit (leuprolide - long-acting formulation) (ODB Formulary) **bicalutamide** ODB - General Benefit (bicalutamide) (ODB Formulary)

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B - Drug Regimen

leuprolide

(Various dosage strengths and dose schedules available.)

Leuprolide*

7.5 mg	EVERY MONTH
or	
22.5mg	EVERY 3 MONTHS
or	
30mg	EVERY 4 MONTHS
or	
45mg	EVERY 6 MONTHS

*Route of administration depends on product brand and formulation. Refer to the leuprolide drug monograph.

AND

bicalutamide	50 mg	PO	Daily

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C - Cycle Frequency

Duration of therapy is dependent on the indication.

- Neoadjuvant - Generally up to 6 months in duration
- Adjuvant - Generally up to 3 years
- Palliative - Continue until disease progression

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Toxicity	Bicalutamide	Leuprolide
Myelosuppression	No adjustment required	
Pneumonitis	Discontinue	
Cardiotoxicity, arterial or venous thromboembolism	Discontinue	
Grade 3 or 4 LFT increases	Discontinue	Hold until recovery then restart. If recurs consider discontinuing
Pituitary apoplexy	No adjustment required	Discontinue

Hepatic Impairment

Leuprolide: No adjustment required. See table above for management of drug-related hepatotoxicity.

Bicalutamide:

	Bicalutamide
Mild	No adjustment needed
Moderate	Caution
Severe	Caution

Renal Impairment

Bicalutamide and leuprolide: No adjustment required

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F - Adverse Effects

Refer to leuprolide, bicalutamide drug monograph(s) for additional details of adverse effects.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life Threatening
• Androgen withdrawal symptoms • Constipation/diarrhea, abdominal pain • Fatigue • Disease flare (may be severe) • Osteopenia/osteoporosis • Urinary Symptoms • Edema • Musculoskeletal pain, headache • Injection site reactions • Cough/dyspnea (may be severe) • Rash • Glucose intolerance	• Pneumonitis • Arterial thromboembolism • Venous thromboembolism • GI obstruction/hemorrhage • Arrhythmia • Cardiotoxicity • Hypersensitivity • ↑ LFTs • Pituitary apoplexy • Seizures • ↑ QTc • Depression (may be severe) • Hepatotoxicity

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G - Interactions

Refer to leuprolide, bicalutamide drug monograph(s) for additional details.

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H - Drug Administration and Special Precautions

Refer to leuprolide, bicalutamide drug monograph(s) for additional details.

Administration (leuprolide):

- Outpatient prescription; administer in Cancer Centre or physician's office.
- Vary injection site.
- For long-acting preparations, reconstitute with supplied diluent immediately before injection as directed (see product monograph).
- Do not give multiple monthly injections together to make up a q3 or q4 month dose, as the release characteristics are different.

Lupron Depot® 7.5 mg, 22.5 mg and 30 mg:

- For Intramuscular use only.
- Usual sites of injection include the anterior thigh, gluteal area or deltoid. Vary injection sites.
- Store at room temperature.

Eligard® 7.5 mg, 22.5 mg, 30 mg, and 4 mg:

- For Subcutaneous use only. Choose an injection site on the abdomen, upper buttocks, or anywhere with adequate amounts of subcutaneous tissue.
- Keep refrigerated, or may be stored at room temperature in original packaging for a period of 8 weeks before administration.
- Allow product to reach room temperature before using.

Administration (bicalutamide):

- Outpatient prescription for home administration
- May be taken with or without food

Warnings/precautions:

Leuprolide:

- **Contraindicated i**n patients with hypersensitivity to the drug, its components or similar nonapeptides
- Some brands may contains benzyl alcohol and may cause local reactions.
- Use with caution in patients with osteoporosis (or risk factors for osteoporosis), diabetes, risk factors for QT prolongation, history of depression, cardiovascular disease, metastatic vertebral lesions and/or urinary tract obstruction due to the risk of disease flare, and in patients at risk of convulsions

Bicalutamide:

- **Contraindicated** in patients with hypersensitivity to the drug or any of its components, in localized prostate cancer undergoing ”watchful waiting”, in females and children.
- Results in fluid retention and should be used with caution in patients with cardiac disease as well as in patients at risk for prolonged QTc.
- Contains lactose; use should be carefully considered in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

Pregnancy & Lactation:

- This regimen is **contraindicated** for use in patients who are or may become pregnant. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is **contraindicated** during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Probable

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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

- Blood glucose/HbA1c; baseline and periodic, especially in diabetic patients
- EKG, Electrolytes (including K, Ca, Mg); baseline, also regular for patients at risk of electrolyte abnormality and QT prolongation
- Liver function tests; baseline and regular
- PSA; baseline and periodic
- Clinical assessment for disease flare, osteoporosis, injection site reactions, fluid retention, pneumonitis, androgen withdrawal effects, psychiatric, cardiovascular, hepatic effects and thromboembolism; at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Hemoglobin; baseline and periodic

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J - Administrative Information

Outpatient prescription; Leuprolide drug administration at Cancer Centre or physician's office

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K - References

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

Crook JM, O'Callaghan CJ, Duncan G, et al. Intermittent androgen suppression for rising PSA levels after radiotherapy. N Engl J Med 2012;367:895-903.

Denham JW, Steigler A, Lamb DS, et al. Short-term neoadjuvant androgen deprivation and radiotherapy for locally advanced prostate cancer: 10-year data from the TROG 96.01 randomised trial. Lancet Oncol 2011;12(5):451-9.

Heidenreich A, Bellmunt J, Bolla M, et al. EAU Guidelines on Prostate Cancer. Part 1: Screening, Diagnosis, and Treatment of Clinically Localised Disease. European Urology 2011;59:61-71.

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

Loblaw DA, Virgo KS, Nam R, et al. Initial Hormonal Management of Androgen-Sensitive Metastatic, Recurrent, or Progressive Prostate Cancer: 2007 Update of an American Society of Clinical Oncology Practice Guideline. J Clin Oncol 2007; 25: 1596-605.

Mottet N, Bellmunt J, Bolla M, et al EAU guidelines on prostate cancer. Part II: Treatment of advanced, relapsing, and castration resistant prostate cancer. European Urology 2011:59;572-83.

May 2025 Updated 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.

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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