Regimen Monograph

A - Regimen Name

BICABSRL Regimen

Bicalutamide-Buserelin

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

buserelin
ODB - General Benefit (ODB Formulary)

bicalutamide
ODB - General Benefit (ODB Formulary)

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B - Drug Regimen

buserelin

6.3 mg	SC depot	EVERY 2 MONTHS
OR		
9.45mg	SC depot	EVERY 3 MONTHS

(Outpatient prescription in buserelin fixed-dose injection kits of 6.3mg and 9.45mg implant)

bicalutamide	50 mg	PO	Daily

(Outpatient prescription in multiples of 50mg tablets)

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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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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

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E - Dose Modifications

Dosage with toxicity

Buserelin: No dose adjustment required in myelosuppression. (Continued on next page)

Bicalutamide:

Toxicity	Action
Myelosuppression	No adjustment required
Pneumonitis	Hold; investigate. If confirmed, discontinue.
Cardiac failure, arterial or venous thromboembolism	Discontinue
Grade 3 or 4 LFT increases	Discontinue

Hepatic Impairment

Hepatic impairment	Bicalutamide	Buserelin
Mild	No adjustment required	No adjustment required; no studies conducted.
Moderate	Caution as extensively metabolized by liver; lower elimination may lead to accumulation	
Severe		

Renal Impairment

Buserelin: No adjustment required; no studies conducted.

Bicalutamide: No adjustment required.

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F - Adverse Effects

Refer to buserelin, 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

• Hypogonadism and symptoms of ↓ testosterone • Disease flare – may be severe (may use short-term antiandrogen therapy for blockade of testosterone flare) • Urinary symptoms • Insomnia • Hypertension • Glucose intolerance • Hyperlipidemia • Anemia • Fatigue • Edema • Musculoskeletal pain • Injection site reactions • Cough, dyspnea (may be severe)	• Heart failure • Arrhythmia (including ↑ QTc) • ↑ Cardiovascular risk • Arterial thromboembolism • Venous thromboembolism • Osteoporosis • Pituitary adenoma • Hypersensitivity • Pneumonitis • ↑ LFTs • GI obstruction/hemorrhage • Depression, mood changes

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G - Interactions

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

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H - Drug Administration and Special Precautions

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

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Blood pressure monitoring in patients with hypertension; regular
- Electrolytes, including calcium and magnesium; baseline, also regularly in patients at risk
- Blood glucose monitoring in diabetic patients or patients at risk of hyperglycemia; baseline and regular
- Liver function tests; baseline and regular
- Clinical toxicity assessment for depression, disease flare, osteoporosis, symptoms of hypogonadism, injection site reactions, fluid retention, pneumonitis, thromboembolism, cardiovascular effects, hypersensitivity or local reactions; regular
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- ECG at baseline for patients at risk of QTc prolongation
- Hemoglobin; baseline and regular
- Monitoring of bone and prostatic lesions; periodic

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J - Administrative Information

Outpatient prescription; Buserelin depot administration at Cancer Centre or physician's office

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K - References

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.

Loblaw DA, Virgo KS, Nam R, et al. Initial Hormonal Management of Androgen-Sensitive Metastatic, Recurrent, or Progressive Prostate Cancer: 2006 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.

October 2016 Replaced regimen category with evidence-informed

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M - Disclaimer

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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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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