Regimen Monograph

A - Regimen Name

BSRL Regimen

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)

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B - Drug Regimen

buserelin

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

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C - Cycle Frequency

Every 2 or 3 months depending on the depot formulation used

- Neoadjuvant - Generally up to 6 months in duration
- Adjuvant - Generally up to 3 years
- Palliative - for non-metastatic disease (for example: rising PSA after radiation), use an intermittent schedule. Otherwise use continuously.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

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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.

See appendix 6 for general recommendations.

Dosage with toxicity

Dosage in myelosuppression: No adjustment required

Hepatic Impairment

No adjustment required; no studies conducted.

Renal Impairment

No adjustment required; no studies conducted.

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F - Adverse Effects

Refer to buserelin 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) • Insomnia • Hypertension • Glucose intolerance • Hyperlipidemia • Anemia • Musculoskeletal pain • Injection site reactions	• ↑ Cardiovascular risk • Heart failure • Arrhythmia (including ↑QTc) • Venous thromboembolism • Osteoporosis • Pituitary adenoma • Hypersensitivity • Depression, mood changes

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G - Interactions

Refer to buserelin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to buserelin 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
- Glucose monitoring in diabetic patients or patients at risk of hyperglycemia; baseline and regular
- Clinical toxicity assessment for depression, disease flare, osteoporosis, symptoms of hypogonadism, injection site reactions, thromboembolism, cardiovascular effects, hypersensitivity or local reactions
- 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; drug 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.

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.

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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