Regimen Monograph

A - Regimen Name

TRIP Regimen

Triptorelin

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	**triptorelin** ODB - General Benefit (triptorelin)

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B - Drug Regimen

The dosage strengths are not additive, due to different release characteristics, and must be selected based on the desired dosing schedule.

triptorelin	3.75 mg	IM	Monthly
OR			
triptorelin	11.25 mg	IM	Every 3 months

Alternative Schedule:

triptorelin	22.5 mg	IM	Every 6 months

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C - Cycle Frequency

Every 1, 3 or 6 months, depending on the formulation

- 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.

Dosage with toxicity

Worst grade of toxicity	Dose modification
Myelosuppression	No adjustment required
Grade 3 / 4 toxicity	Discontinue

Hepatic Impairment

Triptorelin exposure is increased in patients with hepatic impairment. Clinical consequences are unknown.

Renal Impairment

Triptorelin exposure is increased in patients with renal impairment. Clinical consequences are unknown.

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F - Adverse Effects

Refer to triptorelin 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) • Musculoskeletal pain • Glucose intolerance (may be severe) • Anemia • Increased prothrombin time	• QT prolongation • Arterial thromboembolism • Venous thromboembolism • Osteoporosis • Hypersensitivity • ↑ Cardiovascular risk • Pituitary apoplexy • Depression • Seizures

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G - Interactions

Refer to triptorelin drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to triptorelin drug monograph(s) for additional details

Administration:

- Intramuscular injection only; to be given in Cancer Centre or physician's office, drug supplied by outpatient prescription.
- The dosage strengths are not additive, due to different release characteristics, and must be selected based on the desired dosing schedule.
- Vary injection sites.
- Reconstitute the drug vial with 2 mL sterile water for injection (forms a suspension) using a 21–gauge needle or using the single dose delivery system (MIXJECT®). Refer to the triptorelin (Trelstar®) product monograph for detailed instructions.
- Store triptorelin (Trelstar®) at room temperature and protected from light; administer triptorelin suspension right after reconstitution. Any unused portion should be discarded immediately.

Warnings/precautions:

- contraindicated in patients who have a hypersensitivity to gonadotropin releasing hormone or luteinizing hormone-releasing hormone (GnRH or LHRH), GnRH agonist analogs, to this drug or any of its components.
- 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.

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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 and/or HbA1c; baseline and periodic, more frequently in diabetic patients or patients at risk of hyperglycemia
- ECG, electrolytes, including calcium and magnesium; baseline, also regularly in patients at risk of electrolyte abnormality or QT prolongation
- PSA, bone and prostatic lesions; periodic
- Clinical assessment of disease flare, osteoporosis, symptoms of hypogonadism, injection site reactions, thromboembolism, depression, cardiovascular effects; 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; 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.

Heyns CF, Simonin MP, Grosgurin P, et al. Comparative efficacy of triptorelin pamoate and leuprolide acetate in men with advanced prostate cancer. BJU Int 2003;92(3):226-31.

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.

Parmar H, Phillips RH, Lightman SL et al. Randomised controlled study of orchidectomy vs long-acting D-Trp-6-LHRH microcapsules in advanced prostatic carcinoma. Lancet 1985; 2:1201-5.

Triptorelin drug monograph, Cancer Care Ontario.

June 2017 modified drug regimen, drug administration and special precautions sections

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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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