Regimen Monograph

A - Regimen Name

BICATRIP Regimen

Bicalutamide-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) (ODB Formulary)

bicalutamide
ODB - General Benefit (bicalutamide) (ODB Formulary)

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B - Drug Regimen

triptorelin

3.75 mg	IM	EVERY MONTH
or		
11.25 mg	IM	EVERY 3 MONTHS
or		
22.5 mg	IM	EVERY 6 MONTHS

AND

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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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

Toxicity	Action (Triptorelin)	Action (Bicalutamide)
Myelosuppression	No adjustment required	No adjustment required
Grade 3 or 4 toxicity	Discontinue	Discontinue
Pneumonitis	Consider discontinuing	Hold; investigate. If confirmed, discontinue.
Cardiac failure, arterial or venous thromboembolism	Consider discontinuing	Discontinue
Grade 3 or 4 LFT increases	Consider discontinuing	Discontinue

Hepatic Impairment

Hepatic Impairment	Triptorelin	Bicalutamide
Mild	Triptorelin exposure is increased in patients with hepatic insufficiency. Clinical consequences are unknown.	No adjustment needed
Moderate or Severe		Caution; as elimination is lower

Renal Impairment

	Triptorelin	Bicalutamide
Renal impairment	Exposure in increased; clinical consequences are unknown	No dose adjustment required

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F - Adverse Effects

Refer to triptorelin, 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 • Glucose intolerance (may be severe) • Anemia • Edema • Headache, musculoskeletal pain • Fatigue • Constipation/diarrhea • Cough, dyspnea (may be severe) • Nausea and vomiting • Increased prothrombin time	• QT prolongation • Cardiotoxicity • Arterial thromboembolism • Venous thromboembolism • Osteoporosis • Hypersensitivity • ↑ Cardiovascular risk • GI obstruction / hemorrhage • Pituitary apoplexy • Depression • Seizures • Pneumonitis • ↑ LFTs

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G - Interactions

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

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H - Drug Administration and Special Precautions

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

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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
- Liver function tests; baseline and regular
- PSA, bone and prostatic lesions; periodic;
- Clinical assessment for fluid retention, pneumonitis, androgen withdrawal effects, disease flare, osteoporosis, injection site reactions, thromboembolism, depression, cardiovascular and hepatic 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; Triptorelin drug administration at Cancer Centre or physician's office

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K - References

Bicalutamide and triptorelin drug monographs, 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.

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.

January 2018 Added triptorelin q6 month schedule

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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

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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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