Regimen Monograph

A - Regimen Name

BICA Regimen

Bicalutamide

Disease Site	Genitourinary - Prostate
Intent	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	Treatment of metastatic prostate (D2) cancer in combination with surgical or medical castration
Supplementary Public Funding	**bicalutamide** ODB - General Benefit (bicalutamide) (ODB Formulary)

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B - Drug Regimen

bicalutamide	50 mg	PO	Daily

(Outpatient prescription in multiples of 50mg tablets)

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C - Cycle Frequency

CONTINUOUS TREATMENT

Until disease progression or unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

Patients should be advised to avoid direct exposure to excessive sunlight and may consider the use of sunscreens.

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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.

Bicalutamide should be started at the same time as the LHRH analogue for patients who have not had surgical castration. Bicalutamide doses of 150 mg/day should not be used as this increases mortality (phase III localized prostate trials).

Dosage with toxicity

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

No adjustment required in the presence of mild hepatic impairment. Caution should be exercised in moderate to severe hepatic impairment, as bicalutamide is extensively metabolized in the liver. Elimination is lower in subjects with severe hepatic impairment, leading to increased accumulation.

Renal Impairment

No adjustment required.

Dosage in the Elderly

No adjustment required.

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F - Adverse Effects

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

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Androgen deprivation symptoms (may be severe)	• Musculoskeletal pain	• Abdominal pain • Nausea, vomiting • Constipation • Diarrhea • Fatigue	• Arrhythmia • Arterial thromboembolism • Venous thromboembolism • Cardiotoxicity • Increased LFTs

		• Edema • Anemia • Infection • Urinary symptoms • Cough, dyspnea (may be severe) • Dizziness	• Hyperglycemia • GI hemorrhage • GI obstruction • Hypersensitivity • Pneumonitis • Photosensitivity

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G - Interactions

Refer to bicalutamide drug monograph(s) for additional details

- Monitor INR closely with warfarin and adjust warfarin dose accordingly
- Caution with QT prolonging drugs
- Caution with CYP3A4 substrates with a narrow therapeutic range

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H - Drug Administration and Special Precautions

Refer to bicalutamide drug monograph(s) for additional details

Administration:

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

Contraindications:

- Patients with hypersensitivity to the drug or any of its components
- Localized prostate cancer patients undergoing ”watchful waiting”
- Females and children.

Precautions:

- contains lactose; use should be carefully considered in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.
- 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

Pregnancy and lactation:

- **CONTRAINDICATED** in pregnancy and breastfeeding. Patients and their partners should use adequate contraception for at least 130 days after the last dose.
- Fertility effects: Probable. Male fertility impairment may be reversible.

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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

- Liver function tests; baseline and regular
- Electrolytes; baseline, also during treatment for patients at risk of electrolyte abnormality and QT prolongation
- ECG; baseline; also during treatment for patients at risk of QT prolongation
- Blood glucose; especially in diabetic patients; baseline and regular
- Bone density; as clinically indicated
- INR, for patients on warfarin; as clinically indicated
- Clinical assessment for fluid retention, pneumonitis, androgen withdrawal effects, 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 as clinically indicated

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Bicalutamide drug monograph, Cancer Care Ontario.

Denis LJ, Griffiths K. Endocrine treatment in prostate cancer. Semin Surg Oncol. 2000;18:52-74

Goa KL, Spencer CM. Bicalutamide in advanced prostate cancer. Drugs & Aging 1998 May; 12(5): 401-22.

Prostate Cancer Trialists' Collaborative Group. Maximum androgen blockade in advanced prostate cancer: an overview of the randomized trials. Lancet. 2000 Apr 29; 355(92140: 1491-8.

Schellhammer P, Sharafi, R, Block N, et al. Clinical benefits of bicalutamide compared with flutamide in combined androgen blockade for patients with advanced prostatic carcinoma: final report of a double-blind, randomized, muticenter trial. Urology 1997; 50(3): 330-336.

Schellhammer P, Sharifi R, Block N et al. A controlled trial of bicalutamide versus flutamide, each in combination with luteinizing hormone-releasing hormone analogue therapy, in patients with advanced prostate cancer. Urology. May 1995; 45(5): 745-52.

May 2019 Updated emetic risk category

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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.

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