Bicalutamide Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Treatment of advanced prostate cancer in combination with luteinizing-hormone releasing hormone (LHRH) analogue therapy or surgical castration.	C61	00482a	N/A

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Bicalutamide is administered once daily on a continuous basis until disease progression or unacceptable toxicity develops.

Drug	Dose	Route	Cycle
Bicalutamide	50mg	PO	Continuous
Treatment doses should be taken at approximately the same time each day. Swallow whole, do not chew, split or crush. Bicalutamide can be taken with or without food. If a patient vomits or misses a dose of bicalutamide, the patient should be instructed to take the next dose at its scheduled time; an additional dose should not be taken.			

ELIGIBILITY:

- Indication as above

CAUTIONS:

- In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval.
- Patients who receive bicalutamide tablets, and their partners should follow adequate contraception during and for 130 days after bicalutamide therapy.

EXCLUSIONS:

- Hypersensitivity to bicalutamide or any of the excipients
- Co-administration of terfenadine, astemizole or cisapride with bicalutamide is contra-indicated

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant with expertise in the treatment of prostate carcinoma

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Blood glucose

Regular tests:

- FBC, renal and liver profile as clinically indicated
- Blood glucose as clinically indicated

Disease monitoring:
Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- No recommended dose modifications.

Table 1: Dose modification of bicalutamide in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No dose adjustment is needed. Hemodialysis: No dose adjustment is needed.	No dose adjustment is needed.
Recommendations as per Giraud et al 2023	

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

Biclutamide: Minimal **(Refer to local policy)**

PREMEDICATIONS: None

OTHER SUPPORTIVE CARE: No specific recommendations

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

REFERENCES:

1. Schellhammer PF, Sharifi R, Block NL, 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, multicenter trial. Casodex Combination Study Group.Urology 1997;50(3):330-336.
2. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://pubmed.ncbi.nlm.nih.gov/37269847/
3. Bicalutamide Summary of Product Characteristics. Accessed May2025. Available at: https://assets.hpra.ie/products/Human/27525/Licence_PA2315-079-001_13092023124006.pdf v

Version	Date	Amendment	Approved By
1	30/05/2018		Prof Maccon Keane
2	27/05/2020	Reviewed.	Prof Maccon Keane
3	08/08/2025	Reviewed. Updated renal and hepatic impairment in line with Giraud et al. Updated in line NCCP standardisation.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.