BNSSG Health Community's Traffic Light System
Shared Care Guidance

Section 1: Heading

Trust: North Bristol NHS and UHB NHS Trust

Specialty / Department: Urology

Drug: Bicalutamide

For the treatment / management of: Prostate cancer (see treatment schedule)

Section 2: Treatment schedule

Bicalutamide is available as the following preparations;

1. 50mg film-coated tablet
2. 150mg film-coated tablet

Bicalutamide is taken orally as a single daily dose of either 50mg or 150mg once daily (see indications below). Treatment in shared care indications is continuous or until disease progression occurs.

No dose adjustment is required in renal impairment or in patients with mild hepatic impairment.

There is limited experience of use in patients with severe renal impairment (CrCl <30mL/min). Bicalutamide may accumulate in patients with moderate or severe hepatic impairment. Caution is required if using bicalutamide in these patient groups.

Appropriate for shared care;

- 50mg once daily – In combination with LHRHa therapy or surgical castration in men with locally advanced prostate cancer. In combination with LHRHa treatment with bicalutamide should commence at least 3 days before administration of the LHRHa.
- 150mg once daily – Either alone or as an adjuvant to radical prostatectomy or radiotherapy in patients with locally advanced prostate cancer at high risk for disease progression.
- 150mg once daily – Unlicensed indication as monotherapy in metastatic prostate cancer in men willing to accept adverse impact on overall survival and gynaecomastia in the hope of retaining sexual function.

Other indications not requiring shared care;

- 50mg once daily – Unlicensed indication to be used to reduce risk of tumour flare when initiating a LHRH. Given 3 days prior to LHRHa initiation and continued for up to 3 weeks after.
- 150mg once daily – Unlicensed indication in patients with prostate cancer requiring cyto-reduction prior to High Intensity Focused Ultrasound (HIFS). Continued for 8 week course.

Section 3: Monitoring

- Baseline PSA, LFTs and FBC.
- Repeat LFTs on 2 occasions within first 8 months of treatment thereafter every 6 months, or as directed by Secondary care specialist. If signs or symptoms of hepatotoxicity assess LFTs promptly and proceed according to results.
- Repeat PSA as directed by Secondary care specialist.
- Hospital review and follow up as clinically indicated.

Section 4: Side-effects

Refer to SPC for full details http://www.medicines.org.uk/

Bicalutamide no longer has black triangle (▼) status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the CSM.

Very-common (≥ 1 in 10) side-effects include; asthenia, rash, breast tenderness and gynaecomastia

(incidence of gynaecomastia may be as high as 80% and referral for breast bud irradiation is recommended by NICE).

Common (≥ 1/100 to ≤ 1/10) side-effects include; anaemia, anorexia, decreased libido, depression, dizziness, somnolence, hot flushes, abdominal pain, constipation, dyspepsia, flatulence, nausea, alopecia or hirsuitism, dry skin, pruritis, haematuria, impotence, weight gain, chest pain and oedema.

Section 5: Drug interactions

- Bicalutamide may increase the activity of **warfarin** (by competition for protein binding) – monitor INR closely in patients taking concomitant **warfarin**,
- Co-administration of; **terfenadine**, **astemizole** or **cisapride** is **contraindicated**,
  In-vitro studies show that bicalutamide inhibits enzymes of the P450 system and is also metabolised by this system, therefore;
  - Caution is advised with concomitant use of other enzyme inhibitors such as **cimetidine** or **ketoconazole** which could theoretically increase plasma concentration of bicalutamide with the potential for increased incidence of adverse effects,
  - Caution is advised with concomitant use of drugs metabolised by the CYP 3A4 system such as **ciclosporin** or **calcium channel blockers** as dose adjustments may be required.

Section 6: Cautions and special recommendations

- By virtue of its indication bicalutamide should not be used in female patients or children.
- Bicalutamide is contraindicated in patients with known hypersensitivity to the active substance or any of the excipients.
- Bicalutamide is contraindicated in patients taking **terfenadine**, **astemizole** or **cisapride**.
- Bicalutamide is contraindicated in patients with Lapp lactase deficiency or glucose-galactose malabsorption.

Section 7: Advice to the patient

Patients should be advised of common possible side-effects, including; breast tenderness, hot flushes, pruritis, lowered sex drive (libido) and erectile difficulties (impotence).

Report any adverse effects that may be associated with bicalutamide use to their specialist or GP. Patients should be advised of the signs and symptoms of hepatotoxicity and instructed to report these to their GP should they occur.

Section 8: Responsibilities for Secondary Care

1. Assess the patient and establish need for bicalutamide.
2. Discuss anticipated benefits and possible side-effects with the patient.
3. Initiate treatment and decide if the patient is suitable to continue treatment.
4. Baseline blood tests, including; LFT's and PSA.
5. Advise Primary care if LFT and/ or PSA monitoring required in Primary care setting, and if appropriate the frequency of monitoring.
6. Prompt communication with Primary care regarding any changes in treatment.
7. Provide supplies of bicalutamide (for 1 month) until shared care is agreed with the GP.

Section 9: Responsibilities for Primary Care

1. Continue prescribing bicalutamide once treatment has been established by Secondary care (after one month supply from secondary care).
2. Monitoring for adverse drug reactions and, if appropriate, reporting to the CSM.
3. Monitor LFTs and / or PSA if agreed with the specialist to do so.
4. Seek specialist advice if LFTs rise, or if signs/symptoms of hepatic changes occur.
5. Assessment of continued well-being of patient and seek specialist advice if signs of disease

progression (such as bone pain and / or increasing urinary symptoms.
6. Seek specialist advice if intolerable side-effects (e.g. gynaecomastia).
7. For patients receiving bicalutamide 150mg daily as monotherapy - seek specialist advice if loss of sexual function.

Section 10: Contact details

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Section 11: Document details

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Section 12: Collaboration

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Section 13: References

SPC for bicalutamide 150mg film-coated tablets (AstraZeneca UK) [last updated 08/07/2010].
SPC for bicalutamide 50mg film-coated tablets (AstraZeneca UK) [last updated 02/08/2010].
NICE Clinical Guideline 58. Prostate cancer: diagnosis and treatment.