NHS Bassetlaw Clinical Commissioning Group

NHS Doncaster Clinical Commissioning Group

Shared Care Protocol
For
Bicalutamide in the treatment of prostate cancer

Shared care guideline:

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Approved by: Doncaster & Bassetlaw Area Prescribing Committee January 2012

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Approved by: Doncaster & Bassetlaw Area Prescribing Committee January 2019
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Review Date: 3 years from approval

Bicalutamide in the treatment of prostate cancer

Statement of Purpose

This shared care guideline (SCG) has been written to enable the continuation of care by primary care clinicians of patients initiated on antiandrogen bicalutamide in the treatment of prostate cancer by the DBTHFT Secondary Care and transferred to Primary Care for continuation where this is appropriate and in the patients' best interests. Primary care will only be requested to take over prescribing of bicalutamide within its licensed indication unless specifically detailed otherwise below.

	Traffic light system classification			
Drug Class	**Green**	**Amber[A]**	**Amber-G[AG]**	**Red[R]**
Antiandrogen		Bicalutamide		

This guidance applies only for the indication for which the drugs are stated to be used for. It should not be used for other indications listed on the Doncaster & Bassetlaw APC traffic light system or for unlicensed indications for the drug.

Responsibilities of specialist clinician

- Diagnosis, assessment, Initiation and stabilisation of drug therapy
- To ensure patient/guardian/carer is fully informed of potential benefits and side effects of treatment and obtain informed consent, in line with national guidance. Ensure that contra-indications, warnings and interactions are considered prior to initiation of bicalutamide
- Perform baseline blood tests including liver function tests (LFTs) and prostate-specific antigen (PSA) and monitor patient's response to treatment and side effects of treatment
- To provide patient / carer with contact details for support and help if required; both in and out of hours
- To initiate bicalutamide in appropriate patients and provision initial prescriptions – usually a period of not less than 3 months
- To contact patient's GP to request transfer of prescribing responsibility and outline monitoring requirements under shared care and send copy of the shared care guideline.
- To advise the GP regarding continuation of treatment, including the duration of treatment
- To discuss any concerns with the GP regarding the patient's therapy
- The patient to normally remain under the specialists' care but if ongoing specialist co-ordination of the patient's care is not required the specialist must provide access to advice and intervention of that specialist in a more timely manner than via a new referral.
- Write to the GP after every clinic visit detailing whether the medication regime should remain the same or be changed. Specify any products / dose or frequency changes and monitor any side effects
- Report adverse events via the Yellow Card reporting system in the BNF or at https://yellowcard.mhra.gov.uk/

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- Confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised (see appendix for template letter). If the request is declined the GP should write to the specialist detailing the reasons why the request has been declined
- Ensure that new contra-indications, warnings and interactions are considered prior to the GP initiating any additional medication.
- To report any serious adverse reaction to the appropriate bodies e.g. MHRA and the referring specialist
- To continue to prescribe for the patient as advised by the specialist
- Ensure monitoring as indicated in monitoring section below
- To inform the specialist if the patient discontinues treatment for any reason
- To seek the advice of the specialist if any concerns with the patient's therapy and report adverse events to the specialist sharing the care of the patient
- To conduct an annual medication review
- For medication supplied from another provider prescribers are advised to follow recommendations for 'Recording Specialist Issued Drugs on Clinical Practice Systems'
- Stop treatment on advice of specialist, or immediately if intolerable side effects occur provided that it is safer to do so than to continue this therapy
- Report adverse events via the Yellow Card reporting system in the BNF or at https://yellowcard.mhra.gov.uk/

Responsibilities of Patients or Carers

- Discuss potential benefits and side effects of treatment with the specialist. Identify whether they have a clear picture of these from the specialist and to raise any outstanding queries. To be fully involved in, and in agreement with, the decision to move to shared care
- To read the product information given to them
- To take Bicalcutamide as prescribed
- To attend hospital and primary care clinic appointments and to bring monitoring information eg: booklet, patient-held record or information sheet for monitoring (if required) and to alert other clinical staff to the treatment they are receiving. Failure to attend appointments will potentially result in the medication being stopped.
- Present rapidly to the primary care prescriber or specialist should the clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or primary care prescriber whilst taking Bicalutamide
- Inform the specialist, primary care prescriber or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.
- Participate in the monitoring of therapy and the assessment of outcomes, to assist health professionals to provide safe, appropriate treatment

Indication

Cancer of the prostate usually responds to hormonal treatment aimed at androgen depletion. Standard treatments include bilateral orchidectomy, use of a gonadorelin analogue or anti-androgen such as bicalutamide. No entirely satisfactory therapy exists for disease

progression despite this treatment (hormone-refractory prostate cancer) but occasional patients respond to other hormone manipulation e.g. with an anti-androgen as additional treatment in conjunction with an LHRH agonist.
Bicalutamide may be used as monotherapy in advanced disease, or in conjunction with radiotherapy or with a gonadorelin analogue

In January 2014, the National Institute for Clinical Excellence (NICE) published a Clinical Guideline on the diagnosis and management of prostate cancer (CG175).

NICE recommended that anti-androgens should be considered in men with metastatic disease as an alternative to LHRH agonist therapy in those wishing to preserve sexual function. Whilst not first line therapy, combined androgen blockade with LHRH agonist and bicalutamide may be rarely considered. It may be used as hormone treatment following failure of previous radical treatment for localised disease.

Dosage and administration

- Treatment of advanced prostate cancer as monotherapy, or in combination with radiotherapy, 150mg daily.
- Treatment of advanced prostate cancer as part of combined androgen blockade (with orchidectomy or LHRH agonist), 50mg daily.

Bicalutamide is taken orally as a single daily dose.

There is no requirement to adjust the dose in patients with renal impairment or mild hepatic impairment. Increased accumulation may occur in patients with moderate to severe hepatic impairment, and therefore should be used with caution in these patients. All patients receiving bicalutamide will be under the ongoing care (minimum of 6 month review) of a Consultant Urologist or Clinical Oncologist.

Monitoring

Test	Specialist service	Primary Care
LFTs	Baseline Every 6 months	Patients will be provided with blood forms by specialist service and attend the GP for the blood test 1 week prior to attending Outpatient appointment. Blood test results are interpreted by the specialist service.
PSA	Baseline Variable as directed by specialist dependant on clinical condition	
Side effects	Minimum of annually at medication review	Annual medication review

Contra-indications

The details below are not a complete list and the BNF and the SPC remain authoritative

Bicalutamide is contraindicated in females and children

Bicalutamide must not be given to any patient who has shown a hypersensitivity reaction to the active substance or to any of the excipients

Co-administration of terfenadine, astemizole or cisapride with Bicalutamide is contraindicated

Side –effects

The details below are not a complete list and the BNF and the SPC remain authoritative

Bicalutamide is generally well tolerated, with a side effect profile of common reactions similar to placebo in large studies.

Bicalutamide is metabolised by the liver and should be used in caution in patients with significant hepatic dysfunction. Elevated levels of transaminases and jaundice may occur, usually in the first few months of use. For this reason, baseline and 6 monthly liver function testing is required during treatment in addition to PSA monitoring.

Expected anti antrogenic side effects include hot flushes, pruritis, decreased libido, breast tenderness and gynaecomastia. The latter is particularly common and may be ameliorated by the use of breast bud irradiation before starting bicalutamide treatment.

Interactions

The details below are not a complete list and the current BNF and the SPC remain authoritative.

Bicalutamide may potentiate the effect of warfarin. Close monitoring of the INR should be undertaken.
Co-administration with terfenadine, astemizole or cisapride is contra-indicated. (NB Terfenadine and cisapride are no longer available in the UK but may be available outside of the UK).
Bicalutamide inhibits enzymes of the cytochrome p450 system, therefore caution is advised when co-administering enzyme inhibitors such as cimetidine and ketoconazole.

Caution is also advised when co-administering bicalutamide with drugs metabolised predominantly by CYP 3A4. (ciclosporin, calcium channel blockers – these drugs may need dosage reductions and plasma ciclosporin levels should be monitored)

Contacts for Support, education and information

Office Hours –Specialist Tel: Urology Appointments 01302 642535
Out of hours – On-call Tel: Oncology Nurse Answer machine 01302 644667

References

NICE CG175 *The diagnosis and management of prostate cancer January 2014*
BNF 76 September 2018 to remove replaced by NG131
NICE NG131 Prostate cancer: diagnosis and management
Casodex 50mg Summary of Product Characteristics – revised 20.3.2018
Casodex 150mg Summary of Product Characteristics – revised 20.2.2018
Full list of side-effects is given in the Bicalutamide summary of product characteristics (SPC), available from www.emc.medicines.org.uk .

https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

It will be presumed by the referring specialist that the primary care team is operating under this shared care guideline. Should the primary care prescriber feel unable to act under this shared care guideline they should discuss with the specialist requesting the care in the first instance. If after discussion they still feel unable to prescribe then the primary care clinician must notify the specialist in writing.

Shared care for the prescribing of Bicalutamide

Dear Prescriber…… (Patient' s GP)

Patients Name: …….. DOB: …….. NHS No. ……

Address:
……

Your patient is being started on treatment with **Bicalutamide**
dose…….. route……. Date initiated by specialist…….

date when dose is stabilised (usually after a period of 3 months)
……

This treatment can be prescribed by primary care prescribers under the Traffic Light System under the "shared care" arrangements. This shared care guideline has been approved by the Doncaster and Bassetlaw Area Prescribing Groups.

We have chosen to use **Bicalutamide** for the treatment of prostate cancer.

As part of shared care arrangements please can you take a blood test prior to the patient's Secondary care appointment and the results will be reviewed along with the patient's adherence, response and side effects to therapy. A blood form will be provided at the Secondary care appointment for the following test.

Will you also please undertake to prescribe for your patient? The prescriber will be responsible for ensuring monitoring of the patient on the medication being prescribed as per this guideline.

Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by secure email to the specialist named on this letter.
Do not hesitate to contact us if you have any concerns.

Contacts for Support, education and information
Office Hours –Specialist Tel: Urology Appointments 01302 642535
Out of hours – On-call Tel: Oncology Nurse Answer machine 01302 644667
Yours sincerely

Clinician's Name……

Clinician's Title …… Hospital / Dept ……..

Please complete and return to specialist – tick a box to indicate agreement / disagreement

☐ I AGREE to take on shared care of this patient

☐ I DO NOT AGREE to take on shared care of this patient

Signed by GP …….

Print name ……

Practice……Date……