Shared Care Protocol for the Prescription and Supply of Bicalutamide

Version 1.0 – Final

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Document author:	**Robert Hirst, Senior Pharmacist**

Tameside Hospital NHS Foundation Trust and NHS Tameside and Glossop

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1. Introduction

Bicalutamide is a non-steroidal anti-androgen, devoid of other endocrine activity. It binds to androgen receptors and thus inhibits the androgen stimulus. Regression of prostatic tumours results from this inhibition. Bicalutamide demonstrates similar efficacy to LHRH analogues for non-metastatic prostate cancer, but may maintain libido.

Bicalutamide may be considered for shared care arrangements for the treatment of advanced prostate cancer in combination with LHRH analogue therapy or surgical castration and as monotherapy for non-metastatic prostate cancer.

These guidelines will formalise the shared care management of prostate cancer with Bicalutamide.

2. Scope

This shared care document has been developed to facilitate the safe and appropriate prescribing and supply of Bicalutamide in primary and secondary care. It is aimed at all healthcare professionals involved in the prescribing, dispensing and monitoring of Bicalutamide.

3. Clinical condition being treated

Licensed indications: Bicalutamide is licensed for the treatment of advanced prostate cancer in combination with LHRH analogue therapy or surgical castration, and as monotherapy for non-metastatic prostate cancer.

4. Product Information and Treatment Regimen to be used

Dose & Duration of treatment:

50mg daily for combination treatment with LHRH analogue (until disease progression).

150mg daily for monotherapy as:

- Sole treatment for locally advanced or progressive prostate cancer (continuous treatment until disease progression).
- Neoadjuvant treatment for three months pre-radiotherapy.
- Adjuvant therapy to radiotherapy for a total of two years.

5. Regimen Management

Aspects of care for which the Consultant is responsible

- Confirm the diagnosis and establish the need for Bicalutamide
- Discuss benefits and potential side effects of treatment with the patient
- Perform baseline blood tests including liver function tests (LFTs) and prostate-specific antigen (PSA)
- Initiate treatment and request the participation of the GP in shared care
- Prescribe the first 28 days of Bicalutamide treatment
- Monitor response to treatment, including PSA monitoring as appropriate
- Communicate promptly with the GP regarding any changes to treatment
- Stop treatment when indicated, or advise the GP when to stop treatment
- Provide advice and support to the GP if problems occur during treatment

Aspects of care for which the GP is responsible

- Reply promptly to the request from the Consultant for shared care
- Take on continued prescribing of Bicalutamide under shared care agreement after the first 28 days of treatment
- Monitor LFTs every six months. Seek advice from the specialist if LFTs rise significantly
- Assess the continued well-being of the patient, and refer back to the specialist if any signs of loss of efficacy (disease progression) e.g. bone pain, increasing urinary symptoms
- Monitor for adverse effects of treatment

- Stop treatment on the advice of the specialist, or immediately if intolerable side effects occur e.g. gynaecomastia, clinically significant hepatic changes.

6. Adverse effects

For a full list of adverse effects refer to the Summary of Product Characteristics.

Bicalutamide is generally well tolerated. Common side effects include: hot flushes, decreased libido, pruritus, breast tenderness and gynaecomastia. (Incidence of gynaecomastia may be as high as 80% and referral for breast bud irradiation is recommended in the NICE appraisal).

Hepatic changes (elevated LFTs, cholestasis and jaundice) have been observed. Most cases occur within the first six months of therapy, the changes are frequently transient, resolving with continued therapy or following cessation. GP should raise any concerns with the specialist.

7. Drug interactions

Bicalutamide may enhance the effects of **Warfarin** – close monitoring of the INR is required especially at initiation of Bicalutamide or following a dose change.

Caution is advised when Bicalutamide is co-administered with Cimetidine, Ketoconazole, Calcium channel blockers or Ciclosporin.

8. Contraindications

Bicalutamide is contraindicated in women and children, and in patients with known hypersensitivity to the active substance or any of the excipients.

9. Communication and Support

Hospital contacts:

Consultant Urologist – Mr Gerald Collins
Telephone: 0161 922 6713 (Secretary Carole Waterhouse)
e-mail: gerald.collins@stockport.nhs.uk

Urology Specialist Nurse – Kerry Fallon
Telephone: 0161 922 6698
e-mail: kerry.fallon@tgh.nhs.uk

10. Statement of agreement

Shared care is an agreement between the GP and the Consultant. This form is a request by the Consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care and continued prescription of the suggested medication, please make this known to the Consultant within 14 days, stating the nature of your concern.

11. Authors and date prepared

Robert Hirst, Senior Pharmacist with Mr G Collins, Consultant Urologist and Ms K Fallon, Urology Specialist Nurse, Tameside Hospital NHS Foundation Trust. February 2012