**THE SHEFFIELD AREA PRESCRIBING GROUP**

# Shared Care Guideline

## For

## Hormonal Management of Prostate Cancer


**Shared care guideline developed by:**

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**This is guidance on the management of a condition, not a commissioning arrangement**

# Hormonal Management 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 hormonal management of prostate cancer by the urology and oncology departments of STHFT. Primary care will only be requested to take over prescribing of hormonal treatments within licensed indications unless specifically detailed otherwise. See here for guidance in the treatment of prostate cancer: **NICE CG 175**

## Responsibilities of consultant clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent
- To initiate the indicated treatments in appropriate patients
- To prescribe the first month's supply or until patient stable
- To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care guideline
- To advise the GP regarding continuation of treatment, including the length of treatment
- To discuss any concerns with the GP regarding the patient's therapy
- To review patient as clinically appropriate and when requested by patient's GP

## Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care agreement
- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To undertake monitoring as per shared care guideline
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual face to face medication review or more frequent if required
- In the event that the GP is not able to prescribe, or where the SCG is agreed but the consultant is still prescribing certain items e.g. hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems**:** http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording_SIDs_on_practice_clinical_systems%20.pdf

## Responsibilities of Patients and Carers

- To attend hospital and GP clinic appointments
- Present rapidly to the GP or specialist should their clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or GP whilst on treatment
- To read the drug information given to them
- Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

## Preparations and indications

**Anti-androgens**: e.g. bicalutamide: SPC; cyproterone: SPC.
Abiraterone and enzalutamide: N.B. these are classified as Red on the TLDL

**Gonadorelin Analogues (LHrH agonist)**: e.g. triptorelin: SPC, leuprorelin: SPC, goserelin: SPC

**Gonadotrophin Hormone Releasing Antagonists:** e.g. degarelix SPC

## Switching between agents

Men will be discharged on the most appropriate form of androgen deprivation therapy that has resulted in disease control. It would not normally be expected for them to be changed or switched in primary care.

## Dosage
## Contra-indications
## Side-effects
## Interactions

Please refer to the current version of the BNF www.medicinescomplete.com/mc/bnf/current/ and the SPC (available from the Electronic Medicines Compendium www.medicines.org.uk/emc/)

## Monitoring

The consultant will ensure all necessary baseline tests are undertaken, which includes U&Es, FBC, LFTs and PSA levels.

PSA levels should be monitored by the GP on a six monthly basis once the patient has been transferred to primary care management.

Hepatic changes may occur with bicalutamide and cyproterone. For bicalutamide the majority of these are expected to occur within the first 6 months and patients will be transferred when this initial monitoring is complete. Severe hepatic changes and hepatic failure have been observed rarely with both anti-androgens and LFTs should be monitored periodically* during treatment and whenever symptoms suggestive of hepatotoxicity occur. *A reasonable frequency of monitoring LFTs would be at least annually.

## Re-Referral Guidelines

A man with metastatic prostate cancer treated with long-term ADT (androgen deprivation therapy) will inevitably develop castration-resistant disease (CRPC), if he lives long enough.
There have been many advances in the treatment of CRPC and prompt initiation of such treatments can improve both longevity and quality of life through reduced symptoms. Nevertheless, in such a group of elderly men, there will be those who will not be fit enough to benefit from second-line treatment. Most clinical trials have been carried out in men of good performance status. These re-referral guidelines have been formulated to try to ensure men who are at risk of disease-progression and who would benefit from further intervention can be seen promptly and appropriately.

Development of castration-resistant prostate cancer is usually indicated by

1. Rising PSA despite castrate androgen levels (approx. 90% of men)
2. Deteriorating lower urinary symptoms (approx.10% of men)
3. Increasing systemic symptoms (approx.10% of men) such as bone pain, fatigue and anorexia.

Indications for re-referral

1. Rising PSA
2. Lower urinary tract symptoms
3. Systemic symptoms

CRPC is diagnosed if the PSA rises by over 2ng/ml from nadir* in the presence of castrate level of androgen. Please confirm the rise by a second PSA measurement at least a week later and check the testosterone level on this second sample.

*PSA nadir is the lowest PSA following initiation of ADT and usually occurs approximately 6 months into treatment.

Before re-referral to urology/ oncology, the GP should ensure that the PSA criteria have been met (above) and that serum testosterone has been checked. Up to 25% of men on long-term LHrH agonist treatment will not have castrate levels of serum testosterone (<1.7 nmolL-1 or 50 ngdL-1)

## Financial implications

Note: brand prescribing of injectable preparations is recommended to ensure selection of the correct product.

All products can be prescribed on an FP10 and dispensed at a community pharmacy. Alternatively, for the injectable preparations, GPs may claim re-imbursement through the Prescription Pricing Division, under the terms of the statement of fees and allowances (paragraph 44.4), if the item is purchased by the GP. Outpatient appointments at STH will be reduced, but there will be an increase in payments to GPs under the Local Commissioned Service.

## Support, education and information

**Further information may be obtained from:**

- Clinical Nurse Specialists, Royal Hallamshire Hospital Tel: 0114 271 1966
- The contact information for the manufacturers of the products listed can be found in the current version of the BNF or the Electronic Medicines Compendium www.emc.medicines.org.uk

## References


- Electronic BNF www.medicinescomplete.com/mc/bnf/current/
- NICE CG 175
- NICE TA 404
- https://www.ncbi.nlm.nih.gov/pubmed/18309951 -Recommendations of the Prostate Cancer Clinical Trials Working Group


Full prescribing information is given in the relevant summary of product characteristics (SPC), available at www.emc.medicines.org.uk