South West Yorkshire Area Prescribing Committee

CYPROTERONE Shared Care Guideline

Introduction	
General statements	• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between consultant and GP • The GP must reply in writing to the request for shared care within two weeks if unwilling to participate. • The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and GP notes • Shared care should only be considered when the patient's clinical condition is stable or predictable
Indication	▪ Long term palliative therapy when LHRH analogues or orchidectomy is contraindicated, not tolerated or oral therapy preferred ▪ Hot flushes with LHRH analogue therapy or after orchidectomy

Individual's Responsibilities	
Hospital specialist's responsibilities	Initial prescribing By hospital consultant Monitoring ▪ Baseline FBC, U&E, including LFTs & prostate-specific antigen (PSA) ▪ Clinical response to therapy, e.g. bone pain and performance status ▪ Radiology and radio-isotopes (CT scans of abdomen and pelvis and bone scans may be performed) Frequency of PSA monitoring to be specified to GP as this differs between hospital trusts. Recent information from a literature search suggests that patients on androgen deprivation therapy may be at increased risk of adverse cardiovascular events. The risk of breast changes can be reduced by the use of prophylactic low-dose irradiation of the breast area.
General Practitioner's responsibilities	▪ Ensure hospital is notified if unwilling to undertake monitoring when requested ▪ Prescribing following written request from specialist care ▪ Ensure monitoring is undertaken according to shared care guideline and only continue prescribing if patient is compliant with monitoring, blood test results are satisfactory, and no adverse or unwanted side effects. ▪ Refer promptly to hospital specialist when any loss of clinical efficacy occurs or disease progression suspected or if intolerance to therapy occurs.
Monitoring required	Monitor for adverse effects of drug therapy. PSA every 3 months (as specified by hospital consultant). Contact Uro-oncology Services if: ▪ patient has symptoms ▪ if PSA doubles from baseline levels ▪ if there are 2 consecutive increases in PSA ▪ if PSA > 20µg/L

	Monitor adrenocorticol function regularly (every 12 months) as there is some information to suggest possible adrenal suppression with higher doses of cyproterone. **LFTs should be closely monitored - every 6 months (not required when cyproterone used for short-term prevention of tumour flare). If patient reports signs or symptoms of hepatotoxicity, measure LFTs promptly and proceed according to results.**
Information given to the patient	Patients will be provided with appropriate patient information leaflets
Contact details	Documented in letter from specialist care to GP

Product Information

The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics

Dosage	The maximum daily dose is 300mg daily. ▪ Long term palliative therapy where LHRH analogues or orchidectomy are contraindicated, or where oral therapy is preferred: 200-300mg daily in 2 – 3 divided doses. ▪ Hot flushes with LHRH analogue therapy or after orchidectomy: initially 50mg daily, adjusted according to response to 50-150mg daily in divided doses.
Serious adverse effects	Hepatic toxicity including jaundice, hepatitis and hepatic failure has been reported. See monitoring guidelines for further information. Common side effects include fatigue and tiredness. Other ADRs include decreased libido, erectile dysfunction and reversible inhibition of spermatogenesis. Recent information from a literature search suggests that patients on androgen deprivation therapy may be at increased risk of adverse cardiovascular events. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Precautions and contra-indications	Contraindicated in patients with ▪ meningioma or history of meningioma ▪ liver disease including Dubin-Johnson syndrome & Rotor syndrome, and previous or existing liver tumours (only if these are not due to metastases from carcinoma of the prostate) ▪ malignant tumours (except for carcinoma of the prostate) ▪ wasting diseases (with the exception of inoperable carcinoma of the prostate) ▪ existing thromboembolic disorders Use with caution in patients with: ▪ diabetes mellitus ▪ sickle cell anaemia ▪ severe depression Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.
Clinically relevant drug Interactions and their management	▪ Dosage requirements of oral antidiabetics and insulin may be altered because of cyproterone's effects on carbohydrate metabolism. Monitor patient's blood glucose closely when treatment is initiated.