South West Yorkshire Area Prescribing Committee

BICALUTAMIDE 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	▪ Locally advanced prostate cancer at high risk of disease progression ▪ Locally advanced non-metastatic prostate cancer when surgical castration or other medical intervention inappropriate ▪ Ongoing monotherapy for prostate cancer in patients wishing to preserve sexual function ▪ Maximum androgen blockade – use continuously in conjunction with LHRH analogue for 3 months

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. Information from a literature search suggests that patients on androgen deprivation therapy may be at increased risk of adverse cardiovascular events. Consider baseline cardiac function and monitoring as required. 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 to 6 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

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	▪ if PSA > 20µg/L U&Es including LFTs and FBC every 6 months. Contact the hospital specialist if potassium, serum creatinine (unless known to have chronic renal failure) or LFTs are significantly raised.
When and how to discontinue treatment	Consult with hospital specialist.
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	▪ Locally advanced prostate cancer at high risk of disease progression: 150mg once daily ▪ Locally advanced non-metastatic prostate cancer when surgical castration or other medical intervention inappropriate: 150mg once daily ▪ Ongoing monotherapy for patients wishing to preserve sexual function – 150mg daily ▪ Maximum androgen blockade: 50mg daily, in conjunction with LHRH analogue for 3 months
Serious adverse effects	Common side effects include abdominal pain, constipation, nausea, dizziness, decreased appetite, decreased libido, anaemia, hot flushes and gynaecomastia & nipple tenderness. 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	Use with caution in patients with moderate to severe hepatic impairment as increased accumulation may occur. 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	Caution with ciclosporin, calcium channel blockers, cimetidine and ketoconazole. INR should be closely monitored in patients taking warfarin. Refer to the current BNF and www.medicines.org.uk/emc/ for complete and up to date information.