NHS South of Tyne and Wear

serving Gateshead Primary Care Trust, South Tyneside Primary Care Trust and Sunderland Teaching Primary Care Trust

SHARED CARE GUIDELINE

For

Leuprorelin (Prostap 3 DCS®) for advanced hormone dependent prostate cancer

Implementation Date:

Review Date:

This guidance has been prepared and approved for use within Gateshead, South Tyneside and Sunderland in consultation with Primary and Secondary Care Trusts and Local Medical Committees.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe these treatments within a shared care setting

Further copies are available from

Medicines Management Team Loftus House Colima Way Sunderland Tel 5297217

Approved by:

Committee	Date
Gateshead Medicines Management Committee	**4.5.2012**
South Tyneside Medicines Management Committee	
Sunderland Prescribing Group	

Shared Care Protocol Leuprorelin

Name of drug:	**Leuprorelin Acetate**	Form and strength:	**11.25mg injection**
Brand name:	**Prostap 3 DCS®**	BNF Code:	8.3.4.2
Conditions(s) to be treated **Patients with stable prostate cancer suitable for androgen depletion therapy and shared care.**		Aim of treatment Metastatic disease or locally advanced cancer of the prostate is commonly responsive to hormonal treatment designed to deprive the cancer of androgen Provision of treatment in primary care will improve the patient experience by providing care closer to home and will contribute to the transfer of activity out of secondary care.	

Excluded patients	**Progressive disease with rising PSA suggestive of castrate resistant prostate cancer**
Eligibility criteria for shared care	**Following dose and drug stabilisation for at least 3 months**
Initiation	Initiation of treatment will take place in secondary care
Duration of treatment	As agreed with secondary care
Usual Maintenance Dose	11.25mg every 12 weeks by subcutaneous injection into or as directed by secondary care physician
Usual Dose Range	As above
Maximum Dose	As above
Available Strengths (Colours)	
Preparations	One dual chamber pre-filled syringe containing 11.25 mg leuprorelin acetate powder in the front chamber and 1 ml of Sterile Solvent in the rear chamber
Administration	Check the patient's medication sheet to ensure dose and frequency is written and signed by the prescribing doctor. Check no previous reaction to leuprorelin. Explain procedure to the patient. Obtain informed consent. The pre-filled syringe of PROSTAP 3 microsphere powder should be reconstituted immediately prior to administration by subcutaneous or intramuscular injection. To prepare for injection, screw the plunger rod into the end stopper until the end stopper begins to turn. While holding the syringe upright, depress the plunger slowly by pushing the plunger rod until the middle stopper is at the blue line in the middle of the barrel. NOTE: Pushing the plunger rod quickly or over the blue line will cause leakage of the suspension from the needle. Gently tap the syringe on the palm keeping the syringe upright to thoroughly mix the particles to form a uniform suspension. The suspension will appear milky. NOTE: Avoid hard tapping to prevent the generation of bubbles. Remove the sheath and advance the plunger rod to expel the air from the syringe. Inject the entire contents of the syringe subcutaneously or intramuscularly as you would for a normal injection
Cost 28 days (Drug Tariff)	£225.72 per 3 monthly injection (£75.24 per month)
Adverse effects	Adverse events which have been reported infrequently include

	peripheral oedema, pulmonary embolism, hypertension, palpitations, fatigue, muscle weakness, diarrhoea, nausea, vomiting, anorexia, fever/chills, headache (occasionally severe),hot flushes, arthralgia, myalgia, dizziness, insomnia, depression, paraesthesia, visual disturbances, weight changes, jaundice, increases in liver function test values and irritation at the injection site. Changes in blood lipids and alteration of glucose tolerance have also been reported which may affect diabetic control. Thrombocytopenia and leucopenia have been reported rarely. Hypersensitivity reactions including rash, pruritis, urticaria and, rarely, wheezing or interstitial pneumonitis have also been reported. Anaphylactic reactions are rare. Spinal fracture, paralysis, hypotension and worsening of depression have been reported A reduction in bone mass may occur with the use of GnRH agonists. Infarction of pre-existing pituitary adenoma has also been reported rarely after administration of both short- and long-acting GnRH agonists. <u>Men</u>:In cases where a "tumour flare" occurs after leuprorelin therapy, an exacerbation may occur in any symptoms or signs due to disease, for example, bone pain, urinary obstruction etc. These symptoms subside on continuation of therapy. Impotence and decreased libido will be expected with leuprorelin therapy. The administration of leuprorelin is often associated with hot flushes and sometimes sweating. Gynaecomastia has been reported occasionally.
Contra-indications / special precautions	Known hypersensitivity to the product, other LHRH analogues or to any excipients of the product. Development or aggravation of diabetes may occur, therefore diabetic patients may require more frequent monitoring of blood glucose during treatment with Leuprorelin. Hepatic dysfunction and jaundice with elevated liver enzyme levels have been reported. Therefore, close observation should be made and appropriate measures taken if necessary. Spinal fracture, paralysis, hypotension and worsening of depression have been reported. In the initial stages of therapy, a transient rise in levels of testosterone, dihydro-testosterone and acid phosphatase may occur. In some cases, this may be associated with a "flare" or exacerbation of the tumour growth resulting in temporary deterioration of the patient's condition. These symptoms usually subside on continuation of therapy. "Flare" may manifest itself as systemic or neurological symptoms in some cases. In order to reduce the risk of flare, an anti-androgen may be administered beginning 3 days prior to Leuprorelin therapy and continuing for the first two to three weeks of treatment. This has been reported to prevent the sequelae of an initial rise in serum testosterone. Patients at risk of ureteric obstruction or spinal cord compression should be considered carefully and closely supervised in the first few weeks of treatment. These patients should be considered for

	prophylactic treatment with anti-androgens. Should urological/neurological complications occur, these should be treated by appropriate specific measures	
Renal impairment and liver disease	No change of dosing required	
Pregnancy and breast feeding	Not applicable	
Monitoring	Three monthly appointments to: • Administer leuprorelin injections. • Monitor any side effects of treatment.	
Responsibilities	Secondary Care	Review patient until stable & suitable for shared care. Complete section 1 of shared care request form Availability for advice and re-referral Annual review with urology nurse specialist
	G.P.	Complete section 2 of shared care request form Administration of leuprorelin injections Monitor side effects of treatment Re-referral if necessary See service specification for full details
Communications	Consultant	Notification of patient suitable for shared care
	G.P.	Acceptance of patient for shared care Notification of FTA monitoring
Re- referral criteria	Patients will remain under the care of the urology team who will review patients at least 3 monthly. If the patient develops any of the following symptoms, contact the named clinician in the urology team: • Rising PSA (ie 50% rise in baseline PSA in 6 months in 2 consecutive measurements) • Deterioration in lower urinary tract symptoms • Bone pain **If patients develop the following symptoms:** • **Lower limb neurology** • **Suspicion of spinal cord compression** **Contact the Urology on call team on the same day by Telephone to arrange immediate admission at:-** **Freeman Hospital (for Gateshead)** **Sunderland Royal Hospital (for Sunderland)** **Urgent Phone Call for same day referrals :** **0191 5656256 (Sunderland Royal Hospital switchboard)** **0191 2336161 (Freeman Hospital switchboard)** **and ask to speak to Urology on call team**	

Contact details	Advice on patient care can be obtained from: **For Sunderland:** On call Urologist, Sunderland Royal Hospital; 0191 5656256 (Sunderland Royal Hospital switchboard - ask to speak to on call Urologist) **For Gateshead:** Consultants:- Ms A O'Riordan 0191 4453167 and Mr E Paez 0191 4453242 Nurse contacts are:- Lorraine Montgomery, Specialist Nurse Practitioner 0191 4452217 or Urology Nurse Practitioners:- Julie Richardson, Samantha Young or Geoff Cummins Telephone 0191 4452829 or 0191 4453403
Agreed Date **5.4.2012 (GMMC)**	**Expiry date** **5.4.2014 (GMMC)**

Appendix 2 Shared Care Request Form

- **Consultant to complete FIRST SECTION of form**
- **GP to complete SECOND section and RETURN to SECONDARY CARE TRUST CLINICIAN TEAM if transfer declined.**

Section 1

Consultant	
Hospital address	
Contact Phone Number	

Patient's name	
Address	
This patient is stabilised on	
Dose	
Prescription for 28 days supply given on	

Compliance aid YES/NO

Monitored by

Designated community pharmacy

Their treatment has been explained to them and a review has been arranged for

…… ……..

Appointments to continue every …… months

Section 2

Patient's name	
Address	

I **ACCEPT** the proposed Shared Care Agreement for this patient

I do **NOT ACCEPT** the proposed Shared-Care Agreement for this patient

My reasons for not accepting: Please complete this section

Signed ……date……..

Please return to the Secondary Care Trust Clinician team (see contact details above)