SHARED CARE GUIDELINE

For

Leuprolin Acetate 11.25mg Injection – Prostate Cancer

Implementation Date: February 1st 2014

Review Date: August 2015

This guidance has been prepared and approved for use in South Tyneside in consultation with Primary and Secondary Care Trusts, primary care medicines management committees 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

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Approved by:

Committee	Date
South Tyneside Medicines Management Committee	**August 13th 2013**

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 **Module 1 - Patients with stable prostate cancer suitable for androgen depletion therapy and monitoring in primary care.** **Module 2 - Patients with prostate cancer suitable for androgen depletion therapy who remain under the care of the Urologist and may in addition have more complex treatment regimes.**		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. Men: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.

<table>
<tr><td rowspan="2">Responsibilities</td><td>Secondary Care</td><td>Review patient until stable & suitable for shared care.
Complete section 1 of shared care request form
Availability for advice and re-referral
Module 2: Annual review and ongoing monitoring with urology nurse specialist</td></tr>
<tr><td>G.P.</td><td>Complete section 2 of shared care request form
Administration of leuprorelin injections
Monitor side effects of treatment
Re-referral if necessary
Module1: Annual review
See service specification for full details</td></tr>
<tr><td rowspan="2">Communications</td><td>Consultant</td><td>Notification of patient suitable for shared care
Notification of any change to treatment</td></tr>
<tr><td>G.P.</td><td>Acceptance of patient for shared care
Notification of FTA monitoring</td></tr>
<tr><td>Re- referral criteria</td><td colspan="2">Patients should be referred back to secondary care if they have any of the following symptoms:

• Rising PSA (ie 50% rise in baseline PSA in 6 months in 2 consecutive measurements)
• Deterioration in lower urinary tract symptoms
• Bone pain

Patients who have the following symptoms should be re-referred the same day:

• Lower limb neurology
• Suspicion of spinal cord compression

If a patient has a known hormone refractory disease with bone metastasis they should be referred to the Urology on call team based at Freeman Hospital</td></tr>
<tr><td>Contact details</td><td colspan="2">In the first instance advice on patient care can be obtained fro

For South Tyneside: On call Urology oncology specialist nurs 0191 4041000 (ext 2236)

Alternatively, where a patient has been primarily receiving trea in one of the following hospitals, and South Tyneside have not able to offer the information required, patient information can b received from:-

For Sunderland:
On call Urologist, Sunderland Royal Hospital; 0191 5656256 (Sunderland Royal Hospital switchboard - ask to speak to on call Urologist)

For Gateshead:
Specialist Nurse Practitioner</td></tr>
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	or Urology Nurse Practitioners Telephone 0191 4452217/2829 or 0191 4820000 and bleep urology nurse
Agreed Date 13.08.2013	**Expiry date 13.08.2015**