SHARED CARE GUIDELINE

For

Goserelin 10.8mg Implant – 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:	**Goserelin**	Form and strength:	**10.8mg implant**
Brand name:	**Zoladex LA©**	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	**Unstable disease state**
Eligibility criteria for shared care	**Following dose and drug stabilisation for at least 1 month**
Initiation	Initiation of treatment will take place in secondary care
Duration of treatment	As agreed with secondary care
Usual Maintenance Dose	10.8mg every 12 weeks by subcutaneous injection into anterior abdominal wall or as directed by secondary care

	physician
Usual Dose Range	As above
Maximum Dose	As above
Available Strengths (Colours)	
Preparations	10.8mg implant in syringe applicator
Administration	1. Check the patient's medication sheet to ensure Zoladex dose and frequency is written and signed by the prescribing doctor. Check no previous reaction to Zoladex. 2. Explain procedure to the patient. 3. Obtain informed consent. 4. Ask the patient to lay in a comfortable position with the upper part of the body slightly raised. If thin ask the patient to sit forward. 5. Wash hands and apply non-sterile gloves. 6. Examine the foil pouch and syringe for damage. 7. Remove the syringe and check that at least part of the Zoladex implant is visable. 8. Check the Zoladex implant is the prescribed dose. 9. Check the expiry date. 10. Pull the plastic safety tab away from the syringe and discard. 11. Remove the needle cover. 12. Do not attempt to try to remove air bubbles as it is not a liquid and it could result in misplacing the implant. 13. Hold the syringe around the barrel, pinch the abdominal skin below the navel line and insert the needle at an angle of 30c – 45c to the skin with the bevel of the needle facing upwards. 14. Continue to insert into the subcutaneous tissue until the protective shield touches the patient's skin. 15. Depress the plunger until it will not depress any further. This will activate the protective shield. You may hear a click and will feel the shield begin to slide and cover the needle. 16. If the plunger is not fully depressed, the protective shield will not be activated. 17. Withdraw the syringe and allow the protective shield to slide and cover the needle. 18. Do not allow the spring to control withdrawal. 19. Dispose of the syringe in the sharps container. 20. Apply a sterile plaster over the injection site and advise the patient or carer to remove after 12 hours. **Note a local anaesthetic injection is not recommended**
Cost 28 days (Drug Tariff)	£235.00 per 3 monthly implant (£78.33 per month)
Adverse effects	Rare incidences of hypersensitivity reactions, which may include some manifestations of anaphylaxis, have been reported. Arthralgia has been reported. Non-specific paraesthesias have been reported. Skin rashes have also been reported which are generally mild, often regressing without discontinuation of therapy. Pharmacological effects in men include hot flushes and

	sweating and a decrease in libido, seldom requiring withdrawal of therapy. Breast swelling and tenderness have been noted infrequently. Initially, prostate cancer patients may experience a temporary increase in bone pain, which can be managed symptomatically. Isolated cases of spinal cord compression have been recorded. The use of LHRH agonists in men may cause a loss of bone mineral density. Changes in blood pressure, manifest as hypotension or hypertension, have been occasionally observed in patients administered goserelin. The changes are usually transient, resolving either during continued therapy or after cessation of therapy with goserelin. Rarely, such changes have been sufficient to require medical intervention including withdrawal of treatment from goserelin. As with other agents in this class, very rare cases of pituitary apoplexy have been reported following initial administration of goserelin 10.8 mg. Following the administration of goserelin 10.8 mg isolated cases of ureteric obstruction have been recorded.	
Contra-indications / special precautions	Known hypersensitivity to the product, other LHRH analogues or to any excipients of the product. The use of goserelin LA in patients at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and the patients monitored closely during the first month of therapy. Consideration should be given to the initial use of an antiandrogen (e.g. cyproterone acetate 300 mg daily for three days before, and three weeks after commencement of goserelin) at the start of LHRH analogue therapy since this has been reported to prevent the possible sequelae of the initial rise in serum testosterone. If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted.	
Renal impairment and liver disease	No change of dosing required	
Pregnancy and breast feeding	Not indicated in females	
Monitoring	Three monthly appointments to: • Administer Goserelin 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 Module 2: Annual review and ongoing monitoring 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 Module1: Annual review See service specification for full details
Communications	Consultant	Notification of patient suitable for shared care Notification of any change to treatment
	G.P.	Acceptance of patient for shared care Notification of FTA monitoring
Re- referral criteria	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**	
Contact details	In the first instance advice on patient care can be obtained from: **For South Tyneside:** On call Urology oncology specialist nurse 0191 4041000 (ext 2236) Alternatively, where a patient has been primarily receiving treatr in one of the following hospitals, and South Tyneside have not b able to offer the information required, patient information can be 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 or Urology Nurse Practitioners J Telephone 0191 4452217/2829 or 0191 4820000 and bleep urology nurse	
Agreed Date: **August 11th 2014**	**Expiry date: August 2015**	