SHARED CARE GUIDELINE

For

Triptorelin 11.25mg and 22.5mg Injection – Prostate Cancer

Implementation Date: June 1st 2017

Review Date: August 2019

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	**June 13th 2017**

Name of drug:	**Triptorelin (as acetate or pamoate)**	Form and strength:	**Decapeptyl SR powder for suspension is available in three strengths; Decapeptyl SR 3mg for intramuscular (i.m.) injection every 28 days, Decapeptyl SR 11.25mg for i.m. injection every 3 months and Decapeptyl SR 22.5mg for i.m. injection every 6 months.**
Brand name:	**Decapeptyl SR©**	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**		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.	

more complex treatment regimes.	
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	11.25mg every 3 months or 22.5mg every 6 months by intramuscular injection or as directed by secondary care physician
Usual Dose Range	As above
Maximum Dose	As above
Available Strengths (Colours)	Decapeptyl SR 3mg pack green, Decapeptyl SR 11.25mg pack silver, Decapeptyl SR 22.5mg pack orange
Preparations	3mg, 11.25mg and 22.5mg vials with ampoules of 2mL suspension vehicle. The vials contain an overage to ensure that a dose of 3, 11.25 or 22.5mg is administered to the patient. Pharmaceutical form – powder for suspension for injection, sustained release. Boxes contain 1 vial and 1 ampoule with 1 syringe and 2 yellow needles. The injection needle is equipped with a safety shield.
Administration	Check the patient's medication sheet to ensure triptorelin (Decapeptyl SR) dose and frequency is written and signed by the prescribing doctor. Check no previous reaction to triptorelin (Decapeptyl SR). Explain procedure to the patient. Obtain informed consent. The suspension vehicle should be drawn into the syringe provided using the unshielded needle and transferred to the vial containing the powder for injection. The vial should be swirled from side to side until a homogenous suspension is formed and the mixture then drawn back into the syringe without inverting the vial. The injection needle should then be changed and the second needle used to administer the injection. As the product is a suspension, the injection should be administered immediately after reconstitution to prevent sedimentation. The suspension should be discarded if it is not administered immediately after reconstitution. The suspension for injection must be reconstituted using an aseptic technique and only using the ampoule that is provided as the suspension vehicle for Decapeptyl SR. Dispose of the syringe and needles in the sharps container. Apply a sterile plaster over the injection site and advise the patient or carer to remove after 12 hours. Please note a local anaesthetic injection is not recommended.
Cost 28 days (Drug Tariff)	£207.00 per 11.25mg injection; £414.00 per 22.5mg injection; (£69.00 per month)
Adverse effects	As seen with other GnRH agonist therapies or after surgical castration, the most commonly observed adverse events related to triptorelin treatment were due to its expected pharmacological effects. These effects included hot flushes and decreased libido. With the exception of immuno-allergic (rare) and injection site (< 5%) reactions, all adverse events are known to be related to testosterone changes. The following adverse reactions considered as at least possibly related to triptorelin treatment were reported. Most of these events are known to be related to biochemical or surgical castration. Very common: Asthenia, hyperhidrosis, back pain, paraesthesia in lower limbs, libido decreased, erectile dysfunction and hot flush. Common: Nausea, hypertension, dry mouth, injection site reaction (including erythema, inflammation, pain), oedema, weight increased, musculoskeletal pain, pain in extremity, pelvic pain, dizziness,

	headache, depression, mood change, hypersensitivity and loss of libido. Prescribers should consult the Summary of Product Characteristics in relation to other side effects. Triptorelin causes a transient increase in circulating testosterone levels within the first week after the initial injection of the sustained release formulation. With this initial increase in circulating testosterone levels, a small percentage of patients (≤5%) may experience a temporary worsening of signs and symptoms of their prostate cancer (tumour flare), usually manifested by an increase in urinary symptoms (<2%) and metastatic pain (5%), which can be managed symptomatically. These symptoms are transient and usually disappear in one to two weeks. Isolated cases of exacerbation of disease symptoms, either urethral obstruction or spinal cord compression by metastasis have occurred. Therefore, patients with metastatic vertebral lesions and/or with upper or lower urinary tract obstruction should be closely observed during the first few weeks of therapy. The use of GnRH agonists, to treat prostate cancer may be associated with increased bone loss and may lead to osteoporosis and increases the risk of bone fracture.
Contra-indications / special precautions	Hypersensitivity to GnRH (gonadotropin releasing hormone), its analogues or to any of the excipients. Rarely, treatment with GnRH agonists may reveal the presence of a previously unknown gonadotroph cell pituitary adenoma. These patients may present with a pituitary apoplexy characterised by sudden headache, vomiting, visual impairment and ophthalmoplegia. There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as triptorelin. Patients should be informed accordingly and treated as appropriate if symptoms occur. Patients with known depression should be monitored closely during therapy. Initially, triptorelin, like other GnRH agonists, causes a transient increase in serum testosterone levels. As a consequence, isolated cases of transient worsening of signs and symptoms of prostate cancer (tumour flare) and cancer related (metastatic) pain may occasionally develop during the first weeks of treatment and should be managed symptomatically. During the initial phase of treatment, consideration should be given to the additional administration of a suitable anti-androgen to counteract the initial rise in serum testosterone levels and the worsening of clinical symptoms. As with other GnRH agonists, isolated cases of spinal cord compression or urethral obstruction have been observed. Careful monitoring is indicated during the first weeks of treatment, particularly in patients suffering from vertebral metastases, at risk of spinal cord compression, and in patients with urinary tract obstruction. After surgical castration, triptorelin does not induce any further decrease in testosterone levels. Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT prolongation and in those receiving concomitant drugs that might prolong the QT interval, physicians should assess the benefit risk ratio including the potential for torsade de pointes prior to initiating triptorelin. Administration of triptorelin in therapeutic doses results in suppression of the pituitary gonadal system. Normal function is usually restored after treatment is discontinued. Diagnostic tests of pituitary gonadal function conducted during and after discontinuation of therapy with GnRH agonists may therefore be misleading. The use of GnRH agonists may cause a reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with a GnRH agonist may reduce bone mineral loss. No specific data is available for patients with established

	osteoporosis or with risk factors for osteoporosis (e.g. chronic alcohol abuse, smokers, long-term therapy with drugs that reduce bone mineral density, e.g. anticonvulsants or corticosteroids, family history of osteoporosis, malnutrition, e.g. anorexia nervosa). Particular caution is therefore necessary since reduction in bone mineral density is likely to be more detrimental in these patients. Treatment with Decapeptyl SR should be considered on an individual basis and only be initiated if the benefits of treatment outweigh the risk following a very careful appraisal. Consideration should be given to additional measures in order to counteract loss of bone mineral density.	
Renal impairment and liver disease	No change of dosing required	
Pregnancy and breast feeding	Not applicable (male-only indication under consideration)	
Monitoring	**Module 1 and 2** - Three or six monthly appointments to: • Administer Triptorelin injections • Monitor any side effects of treatment **Module 1** - Six monthly PSA testing and annual review at GP surgery. **Module 2** - Urologist responsible for monitoring patients.	
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 triptorelin 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 emergencies covered by Sunderland. Macmillan Urology Cancer Nurse Specialists can be contacted Monday to Friday 9am-5pm on 0191 404 1000 ext 2236 or ext 1197 **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 Telephone 0191 4452217/2829 or 0191 4820000 and bleep urology nurse
Agreed Date Aug 11th 2013	**Expiry date August 2015**