East Lancashire Health Economy Medicines Management Board
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SHARED CARE GUIDELINE

Drug: Goserelin 10.8mg Implant (Zoladex LA)

Introduction

Goserelin 10.8mg implant (Zoladex LA) Indications:

Treatment of prostate cancer in the following settings:

- In the treatment of metastatic prostate cancer
- In the treatment of locally advanced prostate cancer, as an alternative to surgical castration
- As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer
- As neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer
- As adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression

Zoladex LA is not indicated for use in females

N.B. Please see the SPC for detailed information on licensed indications

Please note:

The best interest, agreement and preferences of the patient should be at the centre of any shared care agreement and their wishes followed wherever possible. Patients should be able to decline shared care if, after due consideration of the options, they decide it is not in their best interests.

The provision of shared care prescribing guidelines does not necessarily mean that the GP must agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition.

Referral to the GP should only take place once the GP has agreed to this in each individual case, and the hospital or specialist will continue to provide prescriptions until a successful transfer of responsibilities has occurred. The GP should confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised. The secondary/tertiary provider must supply an adequate amount of the medication to cover the transition period. The patient should then be informed to obtain further prescriptions from the GP.
For those patients commencing treatment for metastatic prostatic cancer, the first month of oral anti-androgen therapy will be prescribed by specialist with the first prescription for goserelin implant to commence and continue by GP unless the GP has declined this.

Background
Goserelin (Zoladex LA) is a synthetic analogue of naturally occurring luteinising-hormone releasing hormone (LHRH). On chronic administration Zoladex LA results in inhibition of pituitary luteinising hormone secretion leading to a fall in serum testosterone concentrations in males. Initially, Zoladex LA like other LHRH agonists transiently increases serum testosterone concentrations.
In men by around 21 days after the first depot injection, testosterone concentrations have fallen to within the castrate range and remain suppressed with treatment every 12 weeks.

Administration of Zoladex LA every 12 weeks ensures that exposure to goserelin is maintained with no clinically significant accumulation.

Produced by Senior Medicines Commissioning Pharmacist ELHE.
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References: Astra Zeneca UK Ltd Zoladex® SmPC last updated 07.02.2017

	In the management of patients with metastatic prostate cancer, Zoladex has been shown in comparative clinical trials to give similar survival outcomes to those obtained with surgical castrations. **This shared care guideline excludes: Use in females**
Form	10.8mg implant in a single dose SafeSystem™ syringe applicator with a protective sleeve
Dose and administration (please refer to BNF / SPCs for full details)	One depot of Zoladex LA injected subcutaneously into the anterior abdominal wall every 12 weeks. No dosage adjustment is necessary for patients with renal or hepatic impairment, or in the elderly. Care should be taken to ensure injection is only given subcutaneously. Treatment course: Ongoing under clinical supervision
Common Adverse Effects (please refer to BNF / SPCs for full details)	**Please refer to the SPC or BNF for full list.** Very Common: Libido decreased, hot flush, hyperhidrosis, erectile dysfunction Common: Glucose tolerance impaired, mood changes, depression, paraesthesia, spinal cord compression, cardiac failure, myocardial infarction, blood pressure abnormalities, rash, bone pain,gynaecomastia, injection site reaction, bone density decreased, weight increased. Uncommon: Drug hypersensitivity, breast tenderness, arthralgia, ureteric obstruction. Rare: Anaphylatic reaction. Very Rare: Pituitary tumour, pituitary haemorrhage, psychotic disorder. Not known: QT prolongation, alopecia.
Contraindications / Cautions (please refer to BNF / SPCs for full details)	**Contraindications:** Hypersensitivty to the active substance or any of the excipients listed in section 6.1 of the SPC **Cautions:** **Please note: patients with a known hypertension or depression should be monitored closely whilst receiving Zoladex.** There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as Goserelin. The use of Zoladex 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. If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted. Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating Zoladex LA.

	The use of LHRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an LHRH agonist may reduce bone mineral loss. Particular caution is necessary in patients with additional risk factors for osteoporosis. Reduction in glucose tolerance has been observed in men receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in patients with pre-existing diabetes mellitus. Myocardial infarction and cardiac failure were observed in a pharmaco-epidemiology study of LHRH agonists used in the treatment of prostate cancer. The risk appears to be increased when used in combination with anti-androgens. Injection site injury has been reported with Zoladex, including events of pain, haematoma, haemorrhage and vascular injury. Monitor affected patients for signs or symptoms of abdominal haemorrhage. In very rare cases, administration error resulted in vascular injury and haemorrhagic shock requiring blood transfusions and surgical intervention. Extra care should be taken when administering Zoladex to patients with a low BMI and/or receiving full anticoagulation medications.
Potentially Serious Drug Interactions (please refer to BNF / SPCs for full details)	Since androgen deprivation treatment may prolong the QT interval, the concomitant use of Zoladex with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated.
Secondary Care Responsibilities	1) Record the person's preferences and concerns in their treatment plan. Patients should be able to decline shared care if, after due consideration of the options, they decide it is not in their best interests. Patients should provide explicit consent and this should be recorded in both the patients notes and on the shared care agreement form. 2) Provide information about the medication to patients, including common side effects, necessary monitoring, and where that monitoring will take place. Also, to keep the patient informed of the process at all stages to ensure continuity of treatment. 3) Continue all necessary physical health monitoring during the initiation period and to monitor effectiveness of medication for and adverse effects, and document in the person's notes. 4) Prescribe and monitor the patient for a minimum period of one month's anti-androgen therapy. 5) Continue to provide prescriptions until a successful transfer of responsibilities to the GP has occurred. The secondary/tertiary provider must supply an adequate amount of the medication to cover the transition period. With consent of the patient. 6) The patient should be informed to obtain prescriptions from the GP after the transition period and must be made fully aware of all necessary monitoring requirements. 7) Conduct an annual face to face medication review for all patients covered by this shared care guidance.

	8) Contact the GP within 3 days of a patient missing a specialist face to face appointment to advise whether treatment should be withheld 9) Accept referrals back from primary care for medication discontinuation. 10) Resume prescribing and monitoring of the patient when a decision for managed withdrawal of treatment has been taken. 11) Continue to provide emergency appointments where patients are receiving prescriptions from their GP and they feel that a prompt assessment or review of their treatment is required. 12) Provide prompt on-going advice to General Practitioners as required without necessarily requiring a new referral. 13) Provide advice to the GP as to the changes in parameters that should trigger urgent referral back to the specialist 14) Telephone details and (if appropriate) secure email addresses for both Secondary and Primary Care should be exchanged and recorded. This should include out-of-hours contact numbers. Patients and their carers should also be provided with contact details for support and help if required; both in and out of hours. 15) Ensure that adequate training and educational support is in place for the primary care multidisciplinary team (in collaboration with the local commissioner of the service pathway i.e. CCG)
Primary Care Responsibilities	**Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.** 1. To consider requests to prescribe under shared care arrangements 2. To provide, the prescription for the first dose for the treatment of prostate cancer or identify any concerns about the request to the prescriber in the specialist team. It is expected that primary care prescribers will not make changes to the dose/formulation, unless it is in consultation with the specialist team. 3. To monitor the patient in accordance with Appendix A and contact the specialist team if results give rise to concern. Any ongoing monitoring requirements for individual patients discharged from secondary care will be identified by the specialist service as part of the discharge information to the GP. 4. To contact specialists within the team where concerns arise about a patient's presentation or when advice is needed. 5. To refer back to secondary care if withdrawal of treatment might be indicated **Circumstances for discontinuation of treatment in Primary Care** 1. As a joint decision with specialist team providing specific advice in case of adverse effect pending assessment. 2. Following non-attendance at annual specialist team review pending that review taking place or if there is failure to engage with the review process.

APPENDIX A

Suggested Monitoring	Frequency
Blood pressure	12 weekly
Blood glucose levels	12 weekly
Bone mineral density	If clinically indicated
ECG (QT interval)	If clinically indicated
Depression	If clinically indicated