South West Yorkshire Area Prescribing Committee

Shared Care Guideline for Gonadorelin analogues (Goserelin, Leuprorelin and Triptorelin) in Prostate Cancer

Introduction	
General Statements	• Depending on the local agreements patients will either receive the first dose in secondary care, or the primary care prescriber will be asked to initiate therapy • The primary care prescriber must reply in writing to the request for shared care within two weeks if unwilling to participate. • The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and general practice notes. • Shared care should only be considered when the patient's clinical condition is stable or predictable.
Indication	**Goserelin (*Zoladex*)** • Metastatic prostate cancer • 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. **Leuprorelin (*Prostap*)** • Metastatic prostate cancer. • Locally advanced prostate cancer, as an alternative to surgical castration. • As an adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. • As an adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression. • As neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. **Triptorelin (*Decapeptyl*)** • Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration. • Treatment of metastatic prostate cancer. • As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. • As neoadjuvant 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.

Individuals Responsibilities	
Hospital Specialist's Responsibilities	**Initial prescribing** • Consider current co-morbidities and risk factors for potential adverse effects eg. cardiovascular disease, fractures & diabetes. • An anti-androgen will be prescribed two weeks before initiation of therapy, and if side effects are tolerable then a gonadorelin analogue can be administered. To prevent the testosterone "flare" an oral anti-androgen (e.g. bicalutamide 50mg daily) can be continued for two weeks following the first injection. • The first injection of goserelin, leuprorelin or triptorelin will be given in the Uro-oncology clinic, or as agreed as local practice. **Monitoring** • Baseline FBC, U&E, including LFTs & prostate-specific antigen (PSA) • Monitor patients during the first month following initiation of gonadorelin analogue. • Clinical response to therapy, e.g. bone pain and performance status • Radiology and radio-isotopes (CT scans of abdomen and pelvis and bone scans may be performed) **Communication** • Responsibilities for, timing and frequency of PSA monitoring to be communicated to primary care prescriber as this may differ between hospital trusts.
Primary Care Prescriber's Responsibilities	• Primary care prescriber to inform hospital specialist if unwilling to undertake monitoring as requested. • Long term prescribing and arrange administration of goserelin, leuprorelin or triptorelin • Monitor for adverse effects of drug therapy and assessment of risk factors for potential adverse effects eg. cardiovascular disease, fractures & diabetes. • PSA monitoring according to local shared care service arrangements (as communicated by hospital specialist). • Refer promptly to hospital specialist when any loss of clinical efficacy occurs or disease progression suspected or if intolerance to therapy occurs.
Monitoring Required	• Monitor for adverse effects of drug therapy. • Patients with diabetes may require more frequent monitoring of blood glucose. • PSA every 3 months, or as specified by hospital specialist. (Responsibility for PSA monitoring as per local shared care service arrangements). Patient to be reviewed by Uro-oncology service if: o patient has symptoms o if PSA doubles from baseline levels o if there are 2 consecutive increases in PSA o if PSA > 20µg/L • U&Es including LFTs and FBC every 6 months. Contact the hospital specialist if potassium, serum creatinine (unless known to have chronic renal failure) or LFTs are significantly raised.
Information given to the	Patients will be provided with appropriate patient information leaflets.

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patient	Patient Information Leaflets for the use of these drugs may be available directly from the manufacturers
Contact Details	Documented in letter from specialist care to primary care prescriber.

Product Information

The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics

Dosage

Therapy should be continuous, even if patient is in remission, unless specified by the hospital specialist. Some patients may benefit from a 'hormone holiday' or intermittent therapy which can give relief from side effects but this should only be undertaken following specialist advice.

Information on administration of these products can be obtained from the relevant manufacturer.

- No dosage adjustment is necessary for patients with renal or hepatic failure.
- Dispose of used syringes in a sharps bin
- Always refer to package insert for full details on administration.

Goserelin (*Zoladex* and *Zoladex* LA)

- *Zoladex* (Goserelin 3.6mg) depot injected subcutaneously (SC) into the anterior abdominal wall **every 28 days**, or
- *Zoladex* LA (Goserelin 10.8mg MR) depot injected SC into the anterior abdominal wall **every 12 weeks**.

Preparation and storage:

- Implant, in pre-filled syringe

Leuprorelin (*Prostap* SR DCS and *Prostap* 3 DCS)

- *Prostap* SR DCS (Leuprorelin 3.75mg) depot administered by subcutaneous (SC) or intramuscular injection (IM) **every 28 days**, or
- *Prostap* 3 DCS (Leuprorelin 11.25mg MR) depot administered by SC injection **every 3 months.**

Preparation and storage:

- **Powder and solvent for suspension for injection, sustained release formulation – requiring reconstitution before injecting.**

Triptorelin (*Decapeptyl* SR 3mg, SR 11.25mg or SR 22.5mg

- ***Decapeptyl* SR 3mg – IM injection every 4 weeks (28 days)**
- ***Decapeptyl* SR 11.25mg – IM injection every 3 months**
- ***Decapeptyl* SR 22.5mg – IM injection every 6 months**

Preparation and storage

- **Powder and solvent for suspension for injection, sustained release formulation – requiring reconstitution before injecting.**

Serious Adverse Effects	**Refer to the current BNF and https://www.medicines.org.uk/emc/for complete and up to date information.**
Precautions and Contra-indications	**Refer to the current BNF and https://www.medicines.org.uk/emc/for complete and up to date information.**
Clinically relevant Drug	**Refer to the current BNF and https://www.medicines.org.uk/emc/for complete and up to date information.**

Interactions and their management	

Goserelin, leuprorelin and triptorelin may either be prescribed on a FP10 and dispensed at a pharmacy, or a primary care prescriber may claim re-imbursement through NHS Prescription Services under the terms of the statement of fees and allowances (paragraph 44.4), if purchased by the practice.