AMBER GUIDANCE FOR PRESCRIBING OF GONADORELIN ANALOGUES AND GONADOTROPHIN RELEASING HORMONE ANTAGONISTS IN THE TREATMENT OF PROSTATE CANCER

1. Background

Metastatic cancer of the prostate usually responds to hormonal treatment aimed at androgen depletion. Standard treatments include use of a gonadorelin analogue, as an alternative to surgery.

The gonadotrophin releasing hormone antagonist, degarelix, is used to treat advanced hormone-dependent cancer. It is preferred option in patients in whom tumour "flare" (associated with initial treatment with gonadorelin analogue) is anticipated to cause problems (see below).

2. Indication

Gonadorelin Analogues

- Locally advanced prostate cancer
- Adjuvant treatment to radiotherapy or radical prostatectomy in patients with high risk localised or locally advanced prostate cancer
- Neoadjuvant treatment prior to radiotherapy in patients with high risk localised or locally advanced prostate cancer
- Metastatic prostate cancer

Gonadotrophin Releasing Hormone Antagonists (Degarelix®) Amber drug – see shared care framework

- Symptomatic, advanced metastatic, high PSA prostate cancer patients who are at risk of impending spinal cord compression or ureteric obstruction

3. Dose/Duration

Patients should be prescribed a licensed treatment, with the lowest acquisition cost. Both HUTH and NLAG currently use Decapeptyl SR® as preferred agent. The first injection will be given by initiating team and if tolerates well information will be provided to GP including when next dose is due, recommended brand and

recommended frequency (this will normally be Decapeptyl SR® 22.5mg every 6 months).

Drug Name	Trade name	Monthly dose	Three monthly dose	Six monthly dose
Goserelin	Zoladex	3.6mg	10.8mg (Zoladex LA®)	N/A
Leuprorelin	Prostap	3.75 mg (Prostap SR DCS®)	11.25mg (Prostap 3 DCS®)	N/A
Triptorelin	Decapeptyl SR®	3mg	11.25mg	22.5mg

4. Contraindications

Treatments are contraindicated in known severe hypersensitivity to the active substance or to any of the excipients of the product

Patients at risk of ureteric obstruction or spinal cord compression should be considered carefully and closely supervised in the first few weeks of treatment with gonadorelin analogues. These patients should be considered for treatment with degarelix or prophylactic treatment with anti-androgens

5. Adverse effects

Most commonly reported adverse effects with treatments include: injection site reactions, decreased libido, erectile dysfunction, testicular atrophy, gynaecomastia, hot flushes, hyperhidrosis, rash, mood changes, depression, insomnia, paraesthesia, musculoskeletal pain and discomfort, anaemia, weight changes, nausea, diarrhoea, changes in blood pressure, heart failure, myocardial infarction, reduction in bone mass. Changes in blood lipids and alteration of glucose tolerance have also been reported which may affect diabetic control. Elevated liver enzymes and hepatic dysfunction have also been reported.

In cases where a "tumour flare" occurs after gonadorelin analogues, an exacerbation may occur in any symptoms or signs due to disease, for example, bone pain, urinary obstruction, weakness of the lower extremities and paraesthesia. These symptoms subside on continuation of therapy.

6. Drug interactions

No recognised drug interactions reported

Details of contraindications, cautions, drug interactions and adverse effects listed for all drugs above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

7. Monitoring

Baseline: U&Es, FBC and PSA levels.

During treatment: PSA levels should be monitored by the specialist on a six monthly basis, increased to 3 monthly if rise in PSA levels > 20%. PSA levels >0.4 in patients with radical prostatectomy should be referred to specialist.

(Phlebotomy may be requested by specialist – results will be reviewed by specialist.)

If the GP suspects the patient is experiencing ureteric obstruction or spinal cord compression the hospital specialist should be contacted.

The GP should refer promptly to hospital specialist when any loss of clinical efficacy occurs, if disease progression suspected.

8. Information for patient

Patients should be informed of risks and benefits of treatment, including frequency of administration, side effects of treatment, symptoms which should be reported to clinician.

9. RESPONSIBILITIES

Stage of Treatment	Hospital Team Responsibilities	GP Responsibilities
Initiation	Assess suitability for treatment and select appropriate treatment. Provide information to patient on treatment required Administer first dose Provide information regarding long term product.	
Maintenance	Monitor response to treatment and advise GP of necessary changes to therapy. Evaluation of ADRs reported by the GP.	Monitor patient for adverse effects and report to specialist team where necessary. Liaise with the hospital team in the event of intolerance to therapy, disease progression or loss of efficacy. Administer treatment as directed by specialist team

Document and version control	**This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.**		
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Version number	Author	Job title	Revision description:
1	Jane Morgan/Sue Spence	Principal pharmacist / Clinical Nurse Specialist	Adapted from HERPC guidance