HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Degarelix

Patient's Name:……..… NHS Number: ……

Patient's Address:……..……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework	
Specialist Prescriber's Name……	Prof Reg. No. ……
Specialist Prescriber's Signature……	Date:……
Where prescriber is <u>not</u> a consultant:	
Consultant's Name: ……	GMC No ……..
Consultant's Signature ……... …….	Date:…….
GP's Signature:……	Date:……..
GP's Name (if different from listed above)……..	

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and **<u>send back to specialist</u>**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at: https://www.hey.nhs.uk/herpc/amber/

1. Background

Prostate cancer is the most common cancer in men and makes up 26% of all male cancer diagnoses in the UK. In 2008, 34,335 men were diagnosed with prostate cancer and there were 9376 deaths from prostate cancer in England, Wales and Northern Ireland. This figure increased to 9632 deaths in 2010.

Degarelix is a selective gonadotrophin releasing hormone antagonist that reduces the release of gonadotrophins by the pituitary, which in turn reduces the secretion of testosterone by the testes. Because gonadotrophin-releasing hormone antagonists do not produce a rise in hormone levels at the start of treatment, there is no initial testosterone surge or tumour stimulation, and therefore no potential for symptomatic flares.

2. Indication

Treatment of adult male patients with advanced hormone-dependent prostate cancer. Symptomatic, advanced metastatic, high PSA prostate cancer patients who are at risk of impending spinal cord compression or ureteric obstruction

3. Dose

Degaralix is administered as an initial 240mg dose which is followed by a monthly maintenance dose of 80mg. The initial 240mg (2x120mg) will be given by the consultant team in the hospital. The maintenance dose of 80mg should be given 28 days later in primary care.

It is given by subcutaneous injection in the abdomen. The injection site should vary periodically. Injections should be given in areas where the patient will not be exposed to pressure e.g. not close to waistband or belt and not close to the ribs.

4. Duration of treatment

Indefinite

5. Contraindications and cautions

Hypersensitivity to the active substance or to any of the excipients

A reduction in glucose tolerance has been observed in men who have had orchiectomy or who have been treated with a GnRH agonist. Development or aggravation of diabetes may occur. Diabetic patients may require more frequent monitoring of blood glucose when receiving androgen deprivation therapy. The effect of degarelix on insulin and glucose levels has not been studied. Monitor HbA1c as per relevant NICE guidance for diabetes 3-6 monthly.

6. Adverse effects

- Hot flushes* (25% patients treated for 1 year)
- Weight increase* (7% of patients treated for 1 year)
- Injection site adverse reactions (site rotation is recommended)
- Transient chills, fever or influenza like illness - reported to occur hours after dosing. Affected patients should be advised to take paracetamol.

- Reduced level of testosterone may cause a reduction in bone calcium and osteoporosis.

Common (≥1/100 to <1/10): anaemia*, insomnia, dizziness, headache, diarrhoea, nausea, raised liver transaminases, hyperhidrosis (including night sweats)*, rash, musculoskeletal pain and discomfort*, gynaecomastia, testicular atrophy*, erectile dysfunction*, , fatigue*,
* known physiological consequence of testosterone suppression

7. Interactions

Drugs that prolong QT interval, antiarrhythmics, methadone, moxifloxacin, antipsychotics. As androgen deprivation treatment may prolong the QTc interval.

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

8. Monitoring

Base line (by specialist): Serum PSA, U&Es, FBC and LFTs

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%. (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.

9. Information to 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.

10. Responsibilities of clinicians involved

Stage of Treatment	Specialist	General Practitioner
Initiation	Assess suitability for treatment and recommend that treatment is initiated Base line: Serum PSA, U&Es, FBC and LFTs Provide information to patient on treatment required Administer first dose – 240mg (2x120mg subcutaneous injections)	

Maintenance	Monitor response to treatment and advise GP of necessary changes to therapy. Evaluation of ADRs reported by the GP. Monitor PSA levels at six monthly intervals, increased to 3 monthly if rise in PSA levels > 20%. (Phlebotomy may be requested by specialist to be done by GP – results will be reviewed by specialist.)	To agree to and prescribe in line with shared care agreement If patient misses Degarelix dose by more than 2 weeks to give initiation dose of 240mg (as 2x120mg as subcutaneous injection and then follow the monthly 80mg schedule thereafter. Measure PSA and send result to secondary care mentioning that the patient has missed regular dose. Arrange regular administration via practice or district nurse. 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. Monitor HbA1c 3-6 monthly.

Contact Details:

During Office hours: Specialist as per clinic letter

Out of hours: On-call registrar for Urology (via switchboard – 01482 875875).

APPROVAL PROCESS

Written by:	***Jane Morgan. Acting Senior Principal Pharmacist – Interface; Updated Jane Morgan – Interface Pharmacist***
Consultation process:	***Consultant urologists HUTH***
Approved by:	***MMIG***
Ratified by:	***HERPC: May 2021***
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