DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
(JAPC)

SHARED CARE AGREEMENT – FRAMEWORK

DEGARELIX in the treatment of adult male patients with advanced hormone-dependant Prostate Cancer

1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient’s GP that the patient’s condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case.
- The patient will be given a starting dose of 240mg administered as two subcutaneous injections of 120mg each in secondary care; further treatment will be provided and administered via the GP Surgery.

2. AREAS OF RESPONSIBILITY

<table>
<thead>
<tr>
<th>GP responsibilities</th>
<th>Consultant responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Monitoring the patients overall health and well-being and observing patient for evidence of ADR/abnormalities and raising with secondary care clinician if necessary</td>
<td>1) Diagnosis of condition and ensuring other treatment options have been fully explored</td>
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<tr>
<td>2) To agree to prescribe in line with the shared care agreement</td>
<td>2) To discuss the benefits and side effects of treatment with the patient/carer</td>
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<tr>
<td>3) To report any adverse reaction to the MHRA</td>
<td>3) To undertake baseline assessment</td>
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<tr>
<td>4) PSA should be measured at 6 monthly intervals</td>
<td>4) To prescribe and administer the starting dose of 240mg as two subcutaneous injections of 120mg each</td>
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<tr>
<td>5) Further prescription and administration of maintenance 80mg dose of degarelix after initiation by secondary care and continued prescription and administration of degarelix unless advised to stop treatment by secondary care</td>
<td>5) To contact the patients GP to request prescribing under shared care using the letter in appendix 1 specifying PSA threshold on an individual basis</td>
</tr>
<tr>
<td>6) If the patient misses his degarelix injection by more than 2 weeks, he should be given the initiation dose of 240mg (as two subcutaneous injections of 120mg each) degarelix and then follow the monthly 80mg degarelix schedule thereafter. PSA should be measured</td>
<td>6) To advise the GP regarding continuation of treatment including the length of treatment</td>
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<tr>
<td>7) Arranging for regular administration by the practice or district nurse</td>
<td>7) To discuss any concerns with the GP regarding the patients therapy</td>
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<tr>
<td>8) Ensuring advice is sought from the secondary care clinician if there is any significant change in the patients physical health status</td>
<td>8) To report any adverse effects to the MHRA yellow card scheme and GP</td>
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<tr>
<td>9) To report any adverse effects to the referring specialist and the MHRA yellow card scheme</td>
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<table>
<thead>
<tr>
<th>Patient responsibilities</th>
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</thead>
<tbody>
<tr>
<td>1) Report any adverse reactions to the GP or specialist whilst receiving treatment with degarelix</td>
</tr>
<tr>
<td>2) Share any concerns in relation to treatment with degarelix</td>
</tr>
<tr>
<td>3) Report to the specialist or GP if they do not have a clear understanding of their treatment</td>
</tr>
<tr>
<td>4) To attend the GP surgery every month for their degarelix injection</td>
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</tbody>
</table>

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:
   Derby Hospitals NHS Foundation Trust
   Telephone No: 01332340131
   Ask for Specialist/secretary or contact urology clinic on 88060
   Fax No: Request from specialist/secretary, as above
   Chesterfield Royal Hospital
   Referring specialist via switchboard 01246 277271

ii. Out of hours contacts and procedures:
    Derby Hospitals NHS Foundation Trust
    Pharmacy, DHFT, ask for on-call pharmacist via switchboard – 01332 340131

iii. Specialist support/resources available to GP including patient information
Degarelix is a gonadotrophin releasing hormone (GnRH) antagonist indicated for the treatment of adult male patients with advanced hormone-dependant prostate cancer. Degarelix will be prescribed for patients requiring a rapid lowering of testosterone presenting with symptoms such as:
- Impending spinal cord compression (as per NICE CG 75)
- Treating advanced hormone dependent prostate cancer in people with spinal metastases (as per NICE TA 404)
- Renal failure due to ureteric obstruction

Degarelix is a selective gonadotrophin releasing-hormone (GnRH) antagonist that competitively and reversibly binds to the pituitary GnRH receptors, thereby rapidly reducing the release of the gonadotrophins, luteinizing hormone (LH) and follicle stimulating hormone (FSH), and thereby reducing the secretion of testosterone (T) by the testes. Prostatic carcinoma is known to be androgen sensitive and responds to treatment that removes the source of androgen. Unlike GnRH agonists, GnRH antagonists do not induce a LH surge with subsequent testosterone surge/tumour stimulation and potential symptomatic flare after the initiation of treatment.

Patients do not require a course of anti-androgens as no tumour flare is caused by degarelix

**Starting dose** (to be prescribed & administered by secondary care)
- 240mg administered as two subcutaneous injections of 120mg each

**Maintenance dose** (to be prescribed & administered in primary care)
- 80mg monthly administered as one subcutaneous injection starting one month after the starting dose & continued monthly

MUST BE GIVEN SUBCUTANEOUSLY; INJECTION BY OTHER ROUTES MAY BE HARMFUL

**Adverse effects**

**Very common (≥1/10):** Hot flush*, injection site adverse events

**Common (≥1/100 to <1/10):** anaemia*, weight increase*, insomnia, dizziness, headache, diarrhoea, nausea, liver transaminases increased, hyperhidrosis (inc. night sweats)*, rash, musculoskeletal pain & discomfort, gynaecomastia*, testicular atrophy*, erectile dysfunction*, chills, pyrexia, fatigue*, influenza-like illness

*known physiological consequence of testosterone suppression

**Monitoring Requirements**

**Baseline - Specialist**
- Serum PSA
- IP (U+E, bone profile, liver function test)
- Full blood count

**Every 6 months – GP**
- PSA
- Missed dose (by more than 2 weeks)
  - PSA

**Action to be taken**

Patients should be referred back to secondary care if they have any of the following symptoms:
- PSA above threshold
- Deterioration in lower urinary tract symptoms
- Bone pain

Patients who have the following symptoms should be re-referred on the same day:
- Lower limb neurology
- Suspicion of spinal cord compression

No formal drug-drug interaction studies have been performed. Since androgen deprivation treatment may prolong the QTc interval, the concomitant use of degarelix with medicinal products known to prolong the QTc interval or medicinal products able to induce torsades de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, cisapride, moxifloxacin, antipsychotics, etc. should be carefully evaluated
<table>
<thead>
<tr>
<th>ix. Contra-indications</th>
<th>None. Caution advised diabetes and in patients susceptible to QT-prolongation (see interactions also)</th>
</tr>
</thead>
<tbody>
<tr>
<td>x. Supply of ancillary equipment</td>
<td>Not required</td>
</tr>
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</table>
| xi. Supply, storage and reconstitution instructions | Degarelix should not be mixed with other medicinal products  
The vials should not be shaken  
**See SPC for instructions on reconstitution & administration**  
**Storage conditions after reconstitution**  
Chemical and physical in-use stability has been demonstrated for 2 hours at 25°C. From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user |
| xii. Prepared and or updated by | Prepared by  
The Shared Care Guideline Group, Derby Hospitals NHS Foundation Trust  
Dr Simon Williams, Consultant Urologist, Derby Hospitals NHS Foundation Trust  
James Hooley, Divisional Lead Pharmacist, Surgery Services, Derby Hospitals NHS Foundation Trust  
Updated in consultation with  
Dr. Simon Williams, Consultant Urologist, Derby Teaching Hospitals NHS Foundation Trust  
David Shipstone, Consultant Urologist, Chesterfield Royal Hospital NHS Foundation Trust  
Kate Linton, Consultant Urologist and prostate cancer lead, Chesterfield Royal Hospital NHS Foundation Trust  
Gail McPhail, Urology Matron, Chesterfield Royal Hospital NHS Foundation Trust  
Angela Brocklehurst, Urology cancer CNS, Chesterfield Royal Hospital NHS Foundation Trust  
This does not replace the SPC, which should be read in conjunction with it.  
Date Prepared: July 2013  
Reviewed: June 2017  
Next Review Date: May 2019 |
DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

Your patient was seen on {Insert date} with a diagnosis of {Insert diagnosis}. I have initiated the following medication {Insert drug name} and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

<table>
<thead>
<tr>
<th>Dose Regimen</th>
<th>Date {Insert medicine name} started</th>
<th>Date for GP to start prescribing {Insert medicine name} from</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA threshold is:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The baseline test results are (if applicable):</td>
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<td></td>
</tr>
</tbody>
</table>

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted the need for monitoring, how monitoring will be arranged, and the roles of the consultant / nurse specialist, GP and the patient in shared care. I confirm the patient has understood and is satisfied with this shared care arrangement at this time.

If you do NOT wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}
**GP RESPONSE TO SHARED CARE** (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

<table>
<thead>
<tr>
<th>Patient:</th>
<th>NHS No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant:</td>
<td>Medicine requested for shared care:</td>
</tr>
</tbody>
</table>

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. **My clinical reasons for declining shared care for this patient are listed in the box below:**

Yours sincerely

{(GP name)
(Surgery)

**Please send a copy of this response to:**

1. The specialist/consultant requesting shared care
2. **AN ANONYMISED COPY OF THIS FORM ONLY** to the Medicines Management Clinical Effectiveness Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: sderccg.derbyshiremedicinesmanagement@nhs.net

(Sending a copy of this form to the Clinical Effectiveness Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).