

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

DEGARELIX in the treatment of adult 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

GP responsibilities	Consultant responsibilities
<ol style="list-style-type: none"> 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 2. To agree to prescribe in line with the shared care agreement 3. PSA should be measured at 6 monthly intervals 4. 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. The first maintenance dose should be given one month after the starting dose 5. If the patient misses their degarelix injection by more than 2 weeks, they 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 6. Arranging for regular administration by the practice or district nurse 7. Ensuring advice is sought from the secondary care clinician if there is any significant change in the patients physical health status 8. To report any adverse effects to the referring specialist and the MHRA yellow card scheme 	<ol style="list-style-type: none"> 1. Diagnosis of condition and ensuring other treatment options have been fully explored 2. To discuss the benefits and side effects of treatment with the patient/carer 3. To undertake baseline assessment 4. To prescribe and administer the starting dose of 240mg as two subcutaneous injections of 120mg each 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 6. To advise the GP regarding continuation of treatment including the length of treatment 7. To discuss any concerns with the GP regarding the patient's therapy 8. To report any adverse effects to the MHRA yellow card scheme and GP
<p>Patient responsibilities</p> <ul style="list-style-type: none"> • Report any other adverse effects to the specialist or GP whilst taking degarelix • Share any concerns in relation to treatment with degarelix • Report to the specialist or GP if they do not have a clear understanding of their treatment • To attend the GP surgery every month for their degarelix injection 	

3. COMMUNICATION AND SUPPORT

<p>i. Hospital contacts: <u>University Hospitals of Derby and Burton NHS Foundation Trust</u> Telephone No: 01332 340131 Ask for Specialist/secretary or contact urology clinic on 88060 Email address: dhft.urologysecretaries@nhs.net <u>Chesterfield Royal Hospital</u> Referring specialist via switchboard 01246 277271</p>	<p>ii. Out of hours contacts and procedures: Pharmacy, RDH, ask for on-call pharmacist via switchboard – 01332 340131 Contact the on-call Medic for the relevant speciality via switchboard: 01246 277271</p>
<p>iii. Specialist support/resources available to GP including patient information: Summary of Product Characteristics (SPC) Firmagon® (<i>Degarelix</i>); <i>Ferring Pharmaceuticals Ltd.</i> Available from e-MC at: Firmagon 80mg Injection - Summary of Product Characteristics (SmPC) - (eMC)</p>	
<p>iv. Local arrangements for referral- As outlined in the GP and consultant/specialist areas of responsibility</p>	

4. CLINICAL INFORMATION

<p>i. Prescribed indications</p>	<p>Degarelix is a gonadotrophin releasing hormone (GnRH) antagonist indicated for the treatment of adult patients with advanced hormone-dependant prostate cancer. Degarelix will be prescribed for patients requiring a rapid lowering of testosterone presenting with symptoms such as:</p> <ul style="list-style-type: none"> • 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 	
<p>ii. Therapeutic summary</p>	<p>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</p>	
<p>iii. Dose & Route of administration</p>	<p>Starting dose (to be prescribed & administered by secondary care)</p> <ul style="list-style-type: none"> • 240mg administered as two subcutaneous injections of 120mg each <p>Maintenance dose (to be prescribed & administered in primary care)</p> <ul style="list-style-type: none"> • 80mg monthly administered as one subcutaneous injection starting one month after the starting dose & continued monthly <p>MUST BE GIVEN SUBCUTANEOUSLY; INJECTION BY OTHER ROUTES MAY BE HARMFUL</p>	
<p>iv. Pregnancy, paternal exposure and breastfeeding</p>	<p><u>Pregnancy and breast-feeding</u> There is no relevant indication for use of degarelix.</p> <p><u>Fertility</u> Degarelix may inhibit fertility as long as the testosterone is suppressed.</p>	
<p>v. Duration of treatment</p>	<p>Indefinite</p>	
<p>vi. Adverse effects</p>	<p>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</p> <p>*known physiological consequence of testosterone suppression</p>	
<p>vii. Monitoring Requirements</p>	<p>Specialist- Baseline</p> <ul style="list-style-type: none"> • Serum PSA • IP (U+Es, bone profile, liver function test) • Full blood count 	<p>GP- Every 6 months or Missed dose (by more than 2 weeks)</p> <ul style="list-style-type: none"> • PSA
<p>viii. Action to be taken</p>	<p>Patients should be referred back to secondary care if they have any of the following symptoms:</p> <ul style="list-style-type: none"> • PSA above threshold • Deterioration in lower urinary tract symptoms • Bone pain <p>Patients who have the following symptoms should be re-referred on the same day:</p> <ul style="list-style-type: none"> • Lower limb neurology • Suspicion of spinal cord compression 	

ix. Clinically relevant drug interactions	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, , moxifloxacin, antipsychotics, etc. should be carefully evaluated
x. Contra-indications	None. Caution advised diabetes and in patients susceptible to QT-prolongation (see interactions also)
xi. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed
xii. Supply of ancillary equipment	Not required
xiii. Supply, storage and reconstitution instructions	<p>Degarelix should not be mixed with other medicinal products THE VIALS SHOULD NOT BE SHAKEN See SPC for instructions on reconstitution & administration</p> <p><u>Storage conditions after reconstitution</u> 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</p>
xiv. To be read in conjunction with the following documents	<ul style="list-style-type: none"> • RMOC Shared Care Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
xv. Prepared and or updated by	<p>Prepared by The Shared Care Guideline Group, University Hospitals of Derby and Burton NHS Foundation Trust Dr Simon Williams, Consultant Urologist, University Hospitals of Derby and Burton NHS Foundation Trust</p> <p>Updated in consultation with Dr. Simon Williams, Consultant Urologist, University Hospitals of Derby and Burton NHS Foundation Trust</p>

This does not replace the SPC, which should be read in conjunction with it.

Date first Prepared: July 2013

Reviewed: May 2022

Next Review Date: April 2025

Hospital No: «HOSPITAL_NUMBER»

NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL

«GP_TITLE» «GP_INITIALS» «GP_SURNAME»

«GP_ADDRESS_1»

«GP_ADDRESS_2»

«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»

«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_POSTCODE»

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.

Dose Regimen	Date {Insert medicine name} started	Date for GP to start prescribing {Insert medicine name} from
PSA threshold is:		
The baseline test results are (if applicable):		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	Yes / No
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	Yes / No
The risks and benefits of treatment have been explained to the patient	Yes / No
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	Yes / No
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	Yes / No
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	Yes / No
I have included with the letter copies of the information the patient has received	Yes / No
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

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*)

* For completeness please record medication on GP clinical system as per guidance- ['Recording medicines prescribed and issued by other Healthcare Providers'](#)

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.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

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:

		Tick which apply
1.	<p>The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care</p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because <i>[insert reason]</i>. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.</p> <p>I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.</p>	
2.	<p>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</p> <p>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.</p> <p>Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you</p>	
3.	<p>A minimum duration of supply by the initiating clinician</p> <p>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</p>	
4.	<p>Initiation and optimisation by the initiating specialist</p> <p>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</p>	
5.	<p>Shared Care Protocol not received</p> <p>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.</p> <p>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</p>	

6.	Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)	
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Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to the specialist/consultant requesting shared care