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Principles of Shared Care Protocols

1 Robust shared care arrangements facilitate the safe transition of medicines for use in a specified condition between secondary and primary care clinicians with the intention that good shared care is safer for the patient, safer for the prescriber and greatly reduces the likelihood of unexpected adverse drug interactions. Shared care arrangements should follow on from initiation of a specified treatment by a hospital consultant.

2 Patients are entitled to expect shared care arrangements to be seamless and not result in them becoming involuntary intermediaries between clinicians in disagreement.

3 The objective of a shared care protocol is to support patient-centred care and in so doing to clarify roles and responsibilities of the involved clinicians

4 Shared care protocols should be brief and to the point, but must contain adequate and up to date information on where, when and who to obtain further information and advice.

5 Patient safety is of paramount importance and so there must be clarity on the responsibilities of the clinicians sharing the care of the patient and the monitoring requirements to be undertaken, including who should be responsible for such monitoring.

6 A consultant will request the GP to take over shared care prescribing by written request or by phone call. If this is done via telephone conversation it should be backed up by written confirmation.

7 If the GP feels uncertain about agreeing to engage in shared care their concerns should initially be shared with the named specialist service. If agreement cannot be reached prescribing should continue in secondary care.

8 Shared care protocols are generally needed only where drugs or conditions require:

- Specialist assessment to enable patient selection and initiation of treatment
- Short or medium term (e.g. 3-6months) specialist monitoring of efficacy or until the patient is stable.
- Short or medium term specialist monitoring of potential drug toxicity or disease state
- Specific long term monitoring for toxicity of potential drug toxicity or disease state

9 Traffic light systems should consistently reflect shared care arrangements

10 Patients will remain under the care of the consultant i.e. they should not be discharged. If the GP or patient wishes to stop the medication the specialist team should be informed.

11 There will be timely communication about the plan to initiate shared care supplemented by a detailed management plan.

12 Shared care will be implemented and agreed via a transfer of care form /letter which is completed and returned in a timely manner.

13 Shared care protocols should not duplicate information that is available in the BNF or other readily available authoritative source such as the summary of product characteristics so as to avoid out of date information being relied upon.

14 Where local policy or usage differs from information in the BNF this should be highlighted in the shared care protocol along with any additional monitoring requirements.

15 Local commissioning, funding and pathway arrangements need to match any clinical shared care arrangements.

16 Shared care protocols will be agreed jointly by primary and secondary care in conjunction with the local medical committee and endorsed by local Area Prescribing Groups/Committees.

17 Area wide shared care arrangements will be supported by collaborative working across the 5 CCGs in SYB towards area wide shared care arrangements

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THE ROTHERHAM AREA PRESCRIBING GROUP

Shared Care Protocol

For

Degarelix (Firmagon) injection 80mg, 120mg powder and solvent for injection (LHRH Antagonist)

Shared care protocol developed by:

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The Rotherham NHS Foundation Trust (TRNHSFT)

Date approved: June 2015

Review Date: 3 years from approval

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THE ROTHERHAM AREA PRESCRIBING GROUP
Shared Care Protocol for Degarelix (Firmagon) injection 80mg, 120mg powder and solvent for injection

Statement of Purpose

This shared care protocol (SCP) has been written to enable the continuation of care by primary care clinicians of patients initiated on Degarelix (LHRH antagonist) by the Urology and Oncology team at the TRNHSFT. Primary care will only be requested to take over prescribing of Degarelix within its licensed indication after it has already been initiated in secondary care (similar to the LHRH agonist).

Indication

Advanced Metastatic Prostate Cancer [Just like LHRH Agonist drugs at present. That is Leuprorelin acetate (Prostap) , Goserelin (Zoladex) and Triptorelin (Decapeptyl)]

Selection of patients

Degarelix should have a restricted use where there is an acute need for immediate testosterone suppression. These include impending spinal cord compression, renal failure due to ureteric obstruction (where nephrostomy is likely to be indicated) or impending urinary retention or where patients are experiencing severe symptoms e.g. severe bone pain which warrant hospitalisation. It may be considered for patients with high volume, high PSA metastatic disease.

Dosage

Starting dose is given in Secondary care TRNHSFT 240mg administered as two subcutaneous injections of 120mg each. This is. The maintenance dose is 80mg once every 28 days and the first 80mg dose should be given one month after the starting dose. Recommend be given and to be continued to in Primary care.

Contra-indications

Hypersensativity
Preganant women

Side –effects

The details below are not a complete list and the BNF and the SPC remain authoritative

The common side effects include:

- hot flashes
- injection site pain, redness, and swelling, especially with the first dose
- weight gain
- increase in some liver enzymes
- tiredness
- hypertension
- back and joint pain
- chills
- urinary tract infection
- decreased sex drive and trouble with erectile function (impotence)

From clinical trial the main adverse effects associated with degarelix are hot flush (26%), weight gain (7%), injection site pain (29%), and erythema (21%). The overall incidence of adverse effects was 58% for degarelix compared to 42% for leuprolide. The higher incidence with degarelix is attributed to higher incidence of injection site reactions. Overall 32% of patients had a reaction after 240mg initial dose with a lower incidence associated with the se of the lower maintenance dose 80mg.
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Monitoring

Recommended that testosterone levels are measured to ensure medical castration levels achieved in mild and moderate liver impaired patients.

Interactions

The details below are not a complete list and the March 2015 BNF (69) and the SPC remain authoritative.

No drug-drug interaction studies were conducted. Degarelix is not a substrate for the human CYP450 system, hence is not an inducer or inhibitor of the CYP450

Responsibilities of consultant clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent. This is particularly important for unlicensed products
- To initiate Degarelix in appropriate patients
- To continue monitoring of initial response to treatment in secondary care
- To prescribe and initiate the first month's supply of treatment of Degarelix

- To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol.
- To advise the GP regarding continuation of treatment, that is to achieve and sustain stability of metastatic prostate cancer
- To discuss any concerns with the GP regarding the patient's therapy
- The patient to remain under the consultants care whilst ever the patient is being prescribed Degarelix

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care agreement
- To report any adverse reaction to the CHM and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual medication review
- In the event that the GP is not able to prescribe, or where the SCP is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Hospital-Only Drugs on Clinical Practice Systems

Re-Referral guidelines

The patient will remain under the care of the consultant and will only be discharged to the GP if he is stable for at least six months after initiating treatment. Discharge will be with written instructions for re-referral as per other metastatic prostate cancer patients as already agreed with CCG shared care policy for patients with stable prostate cancer.

Financial implications

Degarelix can prevent serious health complications of prostate cancer as mentioned under its indication for use. This has significant cost savings.

Ordering information

Primary care will only require to order the Maintenance Degarelix dose of 80 mg. This is to be administered every 28 days after initiation. 80 mg is given as one subcutaneous injection at a concentration of 20 mg/mL

Support, education and information

Further information can be obtained from

References

How to Degarelix drug information
http://www.firmagon.us/assets/full_pi-2cf8bc4f2d7216ec431b83f29b875150.pdf

Patient information
http://www.macmillan.org.uk/Cancerinformation/Cancertreatment/Treatmenttypes/Hormonaltherapies/Individualhormonaltherapies/Degarelix.aspx

NICE
http://www.nice.org.uk/guidance/gid-tag352/resources/prostate-cancer-advanced-hormone-dependent-degarelix-depot-id590

Full list of side-effects is given in the Degarelix summary of product characteristics (SPC), available from www.emc.medicines.org.uk .

(Template letter to GP)

NHS
Rotherham
Clinical Commissioning Group

Dear Doctor

RE: …….. DOB: …… NHS No.

……..

Address: ……..

Your patient is being started on treatment with Degarelix
This treatment can be prescribed by GPs under the Traffic Light System under the "shared care" arrangements. This shared care protocol has been approved by the Rotherham Area Prescribing Group.

http://www.intranet.sheffieldccg.nhs.uk/medicines-prescribing/shared-care-protocols.htm??????

We have chosen to use …..… ……because …….

As part of shared care arrangements please can you monitor xxxxxxx(e.g. FBC, eGFR), adherence, response and side effects to therapy every XX months. Will you also please undertake to prescribe for your patient?
Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by faxing to ……
Do not hesitate to contact us if you have any concerns.
Yours sincerely

Clinician's Name
Clinician's Title

IMPORTANT REMINDER
The prescribing doctor is responsible
for monitoring the patient on the medication being prescribed
_____*please tear here, return to address or fax*

RE:…… DOB:…….. NHS:…….

Address: ……..

☐ I AGREE to take on shared care of this patient

☐ I DO NOT AGREE to take on shared care of this patient

Signed ……
GP Practice……
Date……

Approved by APG: May 2014
Review Date : April 2017