Mid Cheshire Hospitals NHS
NHS Foundation Trust

Shared Care Guideline for Leuprorelin (Prostap SR DCS) for the management of endometriosis and reduction of uterine fibroids prior to surgery.

Please be advised that the Trust discourages the retention of hard copies of policies and procedures and can only guarantee that the policy on the Trust Intranet is the most up to date version

Document Type:	**Guideline**
Version:	**2**
Date of Issue:	**July 2017**
Review Date:	**July 2019**
Lead Director:	**Director of Pharmacy**
Post Responsible for Update:	**Gynaecology Clinician**
Ratifying Committee:	**JMMG**
Ratified by them in the minutes of:	**21st June 2017**
Distribution to:	**All Trust and primary care staff via the Trust Intranet and CCGs**

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Risk Rating		
Who will be affected by this Procedure?	Trust Employees / Patients / Visitors / General practitioners	
Have any existing risk assessments related to this procedure been appropriately updated	No	
Is a new risk assessment required by this procedure?	No	
Does this procedure require Health and Safety training?	No	
Does this procedure require specialist equipment?	No	
Name:	Karen Thomas	Date: 05/05/17

	A Potential Severity (1-5)	**B Likelihood of Occurrence (1-5)**	**C Risk Rating (A x B = C)**
Raw Risk Rating	5	3	**15**
Final Risk rating	5	2	**10**

1 Introduction / Purpose

This shared care agreement is to promote the ongoing care and support for patients prescribed leuprorelin.

These guidelines have been agreed upon by the Joint Medicines Management Committee in consultation with GPs and CCG medicines management representatives.

The guidance is felt to represent a safe level of clinical care for patients requiring treatment with leuprorelin.

After initial prescribing under hospital supervision, under certain circumstances monitoring and prescribing can be undertaken in general practice.

It is the policy of the Trust that no one will be discriminated against on grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. The Trust will provide interpretation services or documentation in other mediums as requested and necessary to ensure natural justice and equality of access.

2 General Document Principles

Leuprorelin is licensed for several indications. This document refers to the licensed indications for the management of endometriosis, including pain relief and reduction of endometriotic lesions and preoperative management of uterine fibroids to reduce their size and associated bleeding.

Leuprorelin promotes the internalisation of gonadotrophin-releasing hormone (GnRH) receptors in the pituitary gland. Initially an increase in Gn output with increased circulating sex hormone levels is observed but within four weeks of therapy the pituitary is devoid of receptors and sex hormones fall.

Dose

Endometriosis - 3.75 mg administered as a single subcutaneous or intramuscular injection every month for a period of 6 months only. Treatment should be initiated during the first 5 days of the menstrual cycle.

Uterine fibroids - 3.75 mg administered as a single subcutaneous or intramuscular injection every month, usually for 3-4 months but for a maximum of six months.

Preparations available

3.75mg prefilled syringe (Prostap SR DCS)

Special considerations

For the indications covered by this document, treatment for longer than 6 months is not recommended because of increased risk of osteoporosis.
Contraceptive precautions should be taken by all women of child-bearing potential throughout therapy.
In women receiving GnRH analogues prior to surgery, the addition of hormone replacement therapy (HRT) has been shown to reduce bone mineral density loss and vasomotor symptoms. Therefore if appropriate HRT may be administered with GnRH analogue therapy after the assessment of the risks & benefits of treatment

Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).

- Hypersensitivity to any of the ingredients or to synthetic Gn-RH or Gn-RH derivatives.
- Contraindicated in women who are or may become pregnant while receiving the drug.
- Should not be used in women who are breastfeeding or have undiagnosed abnormal vaginal bleeding.

Adverse events

Adverse event System – symptom/sign	**Action to be taken Include whether drug should be stopped prior to contacting secondary care specialist**	**By whom**
Gastrointestinal effects (nausea, abdominal pain)	Contact Gynaecologist for advice if required	GP
Headache or light-headedness	Contact Gynaecologist for advice if required	GP
Menopausal symptoms (if premenopausal)	Contact Gynaecologist for advice if required	GP
Increase in menstrual bleeding	Contact Gynaecologist for advice if required	GP

Prescribing responsibility will only be transferred when

- Treatment is for a specified indication and duration.
- Treatment has been initiated and established by the secondary care specialist.
- The patient's initial reaction to and progress on the drug is satisfactory.
- The patient's general physical, mental and social circumstances are such that she would benefit from shared care arrangements

3 Definitions

JMMG – Joint Medicines Management Group

4 Associated Documents

MCHFT Medicines Policy

5 Duties

JMMG

To develop, disseminate and review this shared care documentation.

Clinicians at MCHFT

- Assess patient & establish the need for therapy
- Initiate treatment
- Clinical and biochemical supervision of patient including scheduling of any operations and evaluation of treatment.
- Evaluation of adverse events reported by GP or patient
- Send letter to GP inviting shared care for the patient

- Provision of therapy until shared care is agreed with GP
- Six month review of patient
- Advise GP if patient can safely receive HRT
- Inform patient of effects and adverse effects of therapy

General practitioners

- The GP will notify the consultant if unwilling to accept shared care
- Assessment of continued well-being of patient
- Adverse drug reaction monitoring
- Issue of maintenance prescriptions
- Ensure that practice nurses administering injections have received training relevant to the product
- After 6 months, if the patient fails to attend or surgery is cancelled / postponed, the consultant is informed and the patient referred back for review

Patient

- To attend for their clinic appointments
- To report adverse effects to their Specialist or GP

Associated Documents

British National Formulary
Summary of Product Characteristics – Leuprorelin

6 Consultation and Communication with Stakeholders

- JMMG
- General Practitioners

Referred to **Governance.policies@mcht.nhs.uk**

7 Implementation

This shared care agreement will be implemented via the Trust Intranet and the CCG JMMG members.

8 Education and Training

This shared care agreement will be made available to secondary care and primary care prescribers when patients are commenced on leuprorelin

9 Monitoring and Review

Standard/process/issue required to be monitored	Monitoring and Audit			
	Process for monitoring e.g. audit	Responsible individual /group	Frequency of monitoring	Responsible committee
Shared care agreement	Discussion at JMMG and by exception.	JMMG	Ongoing in response to incidents	JMMG

10 References / Bibliography

11 Appendices

A **Version Control Document**
B **Communication / Training plan**
C **Equality Impact and Assessment Tool**

APPENIDX A - Control Sheet

This must be completed and form part of the document appendices each time the document is updated and approved.

VERSION CONTROL SHEET			
Date dd/mm/yy	**Version**	**Author**	**Reason for changes**
18/11/13	1	Director of pharmacy	New document
18/05/17	2	Director of pharmacy	Document review

APPENDIX B - Training needs analysis

Communication/Training Plan (for all new / reviewed documents)	
Goal/purpose of the communication/training plan	To make all relevant staff aware of shared care agreement
Target groups for the communication/training plan	Relevant MCHFT staff and GPs
Target numbers	20 MCHFT staff
Methodology – how will the communication or training be carried out?	Access to this shared care agreement
Communication/training delivery	Intranet access
Funding	NA
Measurement of success. Learning outcomes and/or objectives	Shared care agreement in place
Review effectiveness – learning outputs	Review of document
Issue date of Document	June 2017
Start and completion date of communication/training plan	September 2017
Support from Learning & Development Services	Nil

For assistance in completing the Communication / Training Plan please contact the MCHT Learning and Development Services

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APPENDIX C - Form 1

Equality Impact Screening Assessment

Please read the Guide to Equality Impact Assessment before completing this form. To be completed and form part of the policy or other document appendices when submitted to governance-policies@mcht.nhs.uk for consideration and approval or to be completed and form part of the appendices for proposals/business cases to amend, introduce or discontinue services.

POLICY/DOCUMENT/SERVICE Shared Care agreement - Leuprorelin

		Yes/ No	Justification and Data Sources
A	**Does the document, proposal or service affect one group less or more favourably than another on the basis of:**		
1	Race, ethnic origins (including gypsies and travellers) or nationality	**n**	
2	Sex	**n**	
3	Transgender	**n**	
4	Pregnancy or maternity	**n**	
5	Marriage or civil partnership	**n**	
6	Sexual orientation including lesbian, gay and bisexual people	**n**	
7	Religion or belief	**n**	
8	Age	**n**	
9	Disability - learning disabilities, physical disability, sensory impairment and mental health problems	**n**	
10	Economic/social background	**n**	
B	**Human Rights – are there any issues which may affect human rights**		
1	Right to Life	**n**	
2	Freedom from Degrading Treatment	**n**	
3	Right to Privacy or Family Life	**n**	
4	Other Human Rights (see guidance note)	**n**	

NOTES

If you have identified a potential discriminatory impact of this document, proposal or service, please complete form 2 or 3 as appropriate.

Date: 04/05/17 **Name: Karen Thomas**

Signature: K. Thomas **Job Title: Director of Pharmacy**

Date: 04/05/17 **Name: Dr Putchakayala**

Signature: K. Putchakayala **Job Title: JMMG Chair**