NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT

Shared care guidelines for Use of
LHRH Agonist treatment in Gynaecology
Monitoring level - AMBER 2 - Prescribe the drug and perform a more intense level of monitoring, e.g. quarterly

Generic and Proprietary/Brand Name	
Goserelin 3.6mg / Triptorelin 3mg / Leuprorelin Acetate 3.75mg *Zoladex* 3.6mg / *Decapeptyl SR* 3mg / *Prostap SR DCS* 3.75mg	
Indications for shared care	
• Management of endometriosis, including pain relief and reduction of endometrial lesions. Evaluation of the hypoestrogenic state prior to oophorectomy • Pre-operative management of uterine fibroids to reduce their size and associated bleeding.	
Specialist Prescribing and Monitoring Responsibilities – summary. Full details in main body of document	**GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities – summary. Full details in main body of document**
None required, but many will be reviewed in clinic 4 months into treatment.	The GP will ensure that the patient is not suffering from unacceptable side effects. Should LHRH agonists be discontinued please contact the appropriate hospital consultant as soon as possible.
Patient Information	
Manufacturer's Patient Information Leaflet with adequate explanation.	
Specialist Contact Details	
Please see relevant consultant letter.	

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
- **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment

These drugs competitively but irreversibly bind to the LHRH receptors in the pituitary giving an initial burst but then complete inhibition of production of LH and FSH.

This results in an initial stimulation (hence the importance of starting the course at the beginning of the menstrual cycle, days 1-5 to avoid any possibility of ovarian hyperstimulation) but fairly quick cessation of production of LH and FSH. This results in no follicle stimulation and hence no oestrogen production, no ovulation and hence no progesterone, which results in a temporary menopausal state with amenorrhoea, endometrial thinning, reduction in bleeding into endometriotic deposits, temporary shrinkage of fibroids, cessation of any symptoms related to PMT, and resolution of any pain resulting from ovarian cycling.

It may take 6-8 weeks for irregular bleeding (induced by the LHRH agonist), and pain to settle.

Side-effects are those of the menopause i.e. hot flushes, headaches, insomnia, dry vagina and also some other e.g. urticarial rash, and risk of osteoporosis if given for longer than 6 months without add-back HRT.

In some instances without detriment to the results required, continuous combined HRT can be added in to reduce these side-effects if present. Tibolone (2.5mg) is the add-back therapy of choice, for which data are more robust to support its prescription, as it appears not to affect the desired outcome of the LHRH agonist.

Generally LHRH agonists are *not* given for more than 6 months (endometriosis) and in many situations are only required for 3-4 months (fibroid shrinkage, diagnosis of PMT).

Licensed use and agreed local off-label use

- Management of endometriosis, including pain relief and reduction of endometrial lesions.
- Preoperative management of uterine fibroids to reduce their size and associated bleeding.

Criteria for Patient Selection

- Patients should have a laparoscopic or strong clinical suspicion of endometriosis and should have discussed the alternative options for the treatment of endometriosis, i.e. danazol, continuous COCP or high dose medroxyprogesterone acetate. They should have had the treatment benefits and possible side effects explained and should have no contraindications to treatment.
- Patients should have had a decision to proceed to hysterectomy or myomectomy (abdominal and hysteroscopic) for fibroids and require shrinkage of fibroids because of size or anaemia. Patients should have had the treatment benefits and possible side effects explained and should have no contraindications to treatment.

Form and strength of preparation

- Goserelin acetate 3.6mg implant for subcutaneous injection
- Triptorelin acetate 3mg for intramuscular injection: available as *Decapeptyl SR* 3mg
- Leuprorelin acetate 3.75mg for subcutaneous or intramuscular injection: available as *Prostap SR* 3.75mg

Prices as listed in current BNF / MIMS
Please refer to the manufacturers' SPCs for current prescribing and administration information - http://www.medicines.org.uk/emc/

Side Effects and Management

Hot flushes, mood changes including depression and vaginal dryness occur frequently; changes in breast size, breast tenderness and hair loss occur occasionally. These menopausal type side-effects can, where clinically appropriate, be lessened by the addition of continuous combined HRT if not contra-indicated and as advised by the consultant concerned with the case.

Adverse effects reported infrequently are peripheral oedema, fatigue, headache (occasionally severe), arthralgia, dizziness, insomnia, paraesthesia, visual disturbances, weight and irritation at injection site. Hypersensitivity reactions including rash, pruritus, urticaria and wheeze (rare) have been reported.

Temporary loss of libido is related to the pharmacological effects of the treatment.

Please refer to the manufacturers' SPCs for full information:
Goserelin 3.6mg SPC Triptorelin 3mg SPC Leuprorelin 3.75mg SPC

Drug Interactions

None reported

Cautions and Contraindications

- Hypersensitivity to any ingredients or to synthetic LHRH / Gn-RH and derivatives
- Pregnancy
- Should not be used in women who are breastfeeding or have undiagnosed abnormal vaginal bleeding

LHRH agonist therapy usually inhibits ovulation but contraception is not ensured, so non-hormonal methods of contraception should be used. Missed doses of LHRH agonist may result in breakthrough bleeding, ovulation and the potential for conception. Patients should see their GP if they suspect they are pregnant and LHRH agonist therapy should be discontinued.

Goserelin | Drugs | BNF | NICE Triptorelin | Drugs | BNF | NICE Leuprorelin acetate | Drugs | BNF | NICE
Goserelin 3.6mg SPC Triptorelin 3mg SPC Leuprorelin 3.75mg SPC

Initiation of therapy and ongoing dose regimen

- To be initiated in hospital by the appropriate Consultant.
- First dose to be given during the first 5 days of menstrual cycle by subcutaneous injection.
- Subsequent doses to be given subcutaneously once every 28 days.

Administration Information

To be administered immediately after reconstitution (leuprorelin / triptorelin)

Duration of therapy / How the treatment will be reviewed and if appropriate, stopped

- Endometriosis - six months
- Preoperative management of fibroids – 3 to 4 months (max. 6 months)

Baseline assessment and ongoing monitoring – by Specialist

None required if given within first 5 days of onset of period

GP / Community Team or other Primary Care monitoring responsibilities

The GP will ensure that the patient is not suffering from unacceptable side effects. Should LHRH agonists be discontinued please contact the appropriate hospital consultant as soon as possible.

Consultant / Specialist prescribing responsibilities
Will prescribe and where possible administer first dose and must inform GP of expected length of course.
GP prescribing responsibilities
To prescribe and administer the second and subsequent doses until course is complete. To prescribe the first and subsequent doses of LHRH agonist after discussion with prescribing consultant where there are difficulties with the first dose being given on hospital premises. The GP has the option of changing to the most appropriate LHRH agonist product in Primary Care.
Indications for referral back to Specialist
• If pain or bleeding still present 3 months into treatment or signs of an acute abdomen at any stage of treatment.
Further information and supporting documents
• Patients may experience irregular pain or bleeding for 6-8 weeks. • This treatment is not contraceptive and where required patients should be advised to use barrier methods of contraception. •

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Date of Approval	November 2023
Reviewed by	Sally Neave / Jen Carroll (formatting review only)
Last review date	September 2017
Date of next review	June 2024

Document history:

Version	Date	Author / Editor	Status	Comment
1.	Nov 2007	Dr Jane Preston, David Todd (JPH), Mr Ed Morris, NNUH / Fiona Marshall TAG Lead Pharmacist NHS Norfolk	Superseded	Therapeutics Advisory Group (TAG) approved.
2.	May 2012	Mr Ed Morris, Mr Sam Mukhopadhyay (NNUH), Dr Nick Oligbo, JPUH / Fiona Marshall TAG Lead Pharmacist NHS Anglia CSU	Superseded	New consultant authors included. "Evaluation of the hypoestrogenic state prior to oophorectomy" added to indications for use. Therapeutics Advisory Group (TAG) approved May 2012.

3.	July 2014	Mr Ed Morris, Mr Sam Mukhopadhyay (NNUH), Dr Nick Oligbo, JPUH / Fiona Marshall TAG Lead Pharmacist, NEL CSU Anglia	Superseded	Updated with NEL CSU logo. Text on the general principles of shared care prescribing added to the top of the document. Feedback from Mr Morris and Mr Mukhopadhyay indicates on-going support for continued use of the document and no other recommendations for changes. Supported by the TAG September 2014
4.0	May – Sept 2017	As for 3.	Current	Minor formatting changes and hyperlinks to manufacturers' SPCs added. Changed text highlighted in Red Font. Sent to authors and QEH for review. No recommendations for further changes received. Continued use supported by the TAG and D&TCG Sept 2017.
5.0	Aug 2021	Jen Carroll, TAG Lead Technician	FINAL	Discussed at August 2021 TAG meeting. Review dates extended for a year from meeting due to covid pressures
6.0	Nov 2023	Sally Neave / Jen Carroll – MO Team NWICB	Final	Transferred to new template and formatted ready for publication on new KNoW website