NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT FRAMEWORK

Shared care guidelines for Triptorelin for the treatment of precocious puberty, menorrhagia and dysmenorrhoea in children

Level 1 – Prescribe drug and perform higher level of monitoring eg 6 monthly review

Generic and Proprietary/Brand Name

Generic – Triptorelin

Brands - Decapeptyl® SR 11.25mg, Decapeptyl® SR 22.5mg, Gonapeptyl Depot® 3.75mg

Indications for shared care

Central Precocious Puberty in children

Specialist Prescribing and Monitoring Responsibilities	GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities
• The initial injection will be prescribed and administered in hospital. • The child should be observed for a few minutes after injection in case of an acute allergic reaction. • Monitoring will be undertaken by an appropriately skilled paediatrician/paediatric endocrinologist. • Each child will be seen prior to their first planned injection in general practice to confirm suitability, and then every 4-6 months, until after discontinuation of treatment. • Responsibility for monitoring general condition, progress in puberty, growth, bone age (XR left hand and wrist), assessment of any other ongoing or evolving endocrinopathy, and exceptionally, pre-injection measurement of FSH, LH and oestradiol or testosterone.	• To prescribe and facilitate the administration of ongoing treatment with the recommended GnRH agonist product, usually long-acting Triptorelin. • To ensure that the injections are not delayed beyond the recommended time period for any reason. Pubertal suppression action of GnRH agonists may be lost if injections are unduly delayed and increases the incidence of adverse effects. The injection can be brought forward by a few days if needed for practical or logistical reasons. • To report any adverse effects of therapy to the supervising Consultant. • To feedback to the Consultant any concerns regarding GnRH agonist prescribing and/or shared care. • Monitoring overall health and well-being

Patient Information

- To ensure they have clear understanding of the prescribed treatment.
- To ensure that injections are administered as per the recommended time interval. Please notify the supervising Consultant and/or GP if the injection is delayed for any reason
- To share any concerns in relation to treatment with the supervising Consultant and/or GP.
- To report any adverse effects to the supervising Consultant and/or GP whilst on treatment.

The decision to start treatment is based on a full discussion with patients and their families. The process by which treatment is initiated in hospital and continued by the General Practitioner will be explained. Appropriate written information (including copy correspondence) will be provided.

Specialist Contact Details

In case of concern regarding a patient's care, please contact supervising Consultant or deputy as soon as possible:

- Jenny Lind Children's Department, Norfolk & Norwich University Hospital, Colney Lane, Norwich, NR4 7UY. Telephone 01603 286357 (24 hours)
- Dr Vipan Datta - 01603 286349 - vipan.datta@nnuh.nhs.uk
- D Emma Webb - 01603 286341 - Emma.webb@nnuh.nhs.uk
- Dr Ravi Alanoor - 01603 286341 - ravi.alanoor@nnuh.nhs.uk
- Dr Ellada Sotiradou 01603 286349 ellada.sotiradou@nnuh.nhs.uk

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
Gonadotrophin-releasing hormone analogues, such as Goserelin (Zoladex®), Leuprorelin (Prostap®) and Triptorelin (Decapeptyl®, Gonapeptyl®), are the preferred modality of treatment for suppression of FSH and LH secretion in a range of disorders, including prostate cancer, endometriosis and precocious puberty. They have been used in treatment of precocious puberty since the late 1970s and are well established as efficacious and safe, with negligible side-effects. Triptorelin has been licensed for the treatment of precocious puberty for some time. Leuprorelin (Prostap®) has also become licensed for treatment of central precocious puberty in girls under 9 years of age and in boys under 10 years of age. Gonadotrophin-releasing hormone (GnRH) stimulates Follicle Stimulating Hormone (FSH) and Luteinising Hormone (LH) release by pituitary gonadotrophs in a pulsatile manner. Non-pulsatile stimulation of the GnRH Receptor by long-acting analogues leads to rapid receptor internalisation and loss of responsiveness to GnRH, after an initial stimulatory effect. The abolition of FSH and LH secretion in turn reduces gonadal sex steroid production (oestrogens or testosterone). This in turn suppresses hormonal changes of puberty.
Licenced use and agreed local off-label use
Central Precocious Puberty in a child below 7 years of age
Criteria for Patient Selection
• Central Precocious Puberty in a child below 7 years of age • Early Puberty in a girl below 9 years, or a boy below 10 years, occasioning psychological, behavioral or emotional distress • Severe Menorrhagia and/or dysmenorrhea in a girl below 13 years • In cases where puberty needs to be delayed in order to maximise growth potential in growth hormone deficient children
Form and strength of preparation
• Gonapeptyl Depot® 3.75mg, given every 4 weeks (see under Initial dose and administration) • Decapeptyl®SR 11.25mg, given every 3 months (12 weeks) • Decapeptyl® SR 22.5mg given every 6 months (24 weeks) • (Decapeptyl® SR 3mg given every 4 weeks is not licensed for precocious puberty)
Side Effects
Triptorelin SPC
Drug Interactions (add links to BNF and SPC)
Triptorelin SPC
Cautions and Contraindications (add links to BNF and SPC)
Triptorelin SPC
Initiation of therapy
Consultant Paediatric Endocrinologist

Initial dose and method of administration and supply

- The first injection(s) of GnRH agonists will be administered in hospital. This is sometimes given as Gonapeptyl Depot® monthly for 3 months.

- Decapeptyl® SR 22.5mg may be given initially and given again at 24 weeks, or 11.25mg may be given initially and then given again at 12 weeks

- The maintenance dose will usually be Decapeptyl® SR 11.25mg every 12 weeks or Decapeptyl® SR 22.5mg every 24 weeks

Maintenance Dose and Administration

Assuming the initial injection(s) is (are) tolerated satisfactorily, the patient's GP will then be asked to continue treatment with the three-monthly preparation (Decapeptyl® SR 11.25mg), by intramuscular injection, every 12-13 weeks. Breakthrough symptoms may necessitate increasing injection frequency, typically up to every 10 weeks or, 6 monthly preparation (Decapeptyl® SR 22.5mg) every 20-24 weeks.

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

Treatment is normally continued until the child and family are emotionally ready for puberty to resume. In girls, this is typically between 10-11 years, and in boys, 11-12 years.

Where treatment has been commenced for severe menorrhagia and/or dysmenorrhoea, treatment is normally stopped around 13 years.

The decision to stop treatment is dependent on individual circumstances. Only in exceptional circumstances would treatment be continued beyond 13 years (girls) or 14 years (boys).

Initial monitoring / baseline assessment – by Specialist

The child should be observed for a few minutes after injection in case of an acute allergic reaction.

Specialist monitoring responsibilities

Monitoring will be undertaken by an appropriately skilled paediatrician/paediatric endocrinologist. Each child will be seen prior to their first planned injection in general practice to confirm suitability, and then every 4-6 months, until after discontinuation of treatment.

Responsibility for monitoring general condition, progress in puberty, growth, bone age (XR left hand and wrist), assessment of any other ongoing or evolving endocrinopathy, and exceptionally, pre-injection measurement of FSH, LH and oestradiol or testosterone.

GP / Community Team or other Primary Care monitoring responsibilities

Symptoms of treatment breakthrough may occur; usually emotional lability and less commonly, progressive pubertal changes. Should there be such concerns, increasing injection frequency to every 10-11 weeks is recommended in the first instance.

Monitoring overall health and well-being.

Consultant / Specialist prescribing responsibilities

The initial injection will be prescribed and administered in hospital.

GP prescribing responsibilities

- To prescribe and facilitate the administration of ongoing treatment with the recommended GnRH agonist product, usually long-acting Triptorelin.
- To ensure that the injections are not delayed beyond the recommended time period for any reason. Pubertal suppression action of GnRH agonists may be lost if injections are unduly delayed and increases the incidence of adverse effects. The injection can be brought forward by a few days if needed for practical or logistical reasons.
- To report any adverse effects of therapy to the supervising Consultant.

- To feedback to the Consultant any concerns regarding GnRH agonist prescribing and/or shared care.

Indications for referral back to Specialist

- Intolerance of the injections.
- Breakthrough symptoms occurring on 10-weekly injections.

Further information and supporting documents

The monthly preparation given by the hospital specialist (Gonapeptyl Depot® 1.875mg – 3.75mg, or Decapeptyl® SR 3mg (off-label use)) may be administered by intramuscular or subcutaneous injection.
The long-acting preparation (Decapeptyl® SR 22.5mg), given by the GP, is administered by intramuscular injection.

Both products are supplied as a dry powder. The manufacturer's recommended method of preparation and administration should be strictly followed; including advice that once prepared the injection should be used immediately.

Reconstitution should only be done with the provided solution and needles should be changed for withdrawing the solution and giving the injection as per manufacturer's recommendations. Use of needles of a gauge narrower than those supplied by the manufacturer is not recommended as the needle may become blocked by the suspended particles of the prepared products.

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Document history:

Version	Date	Author / Editor	Status	Comment
1	July 2007	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, NNUH / Fiona Marshall TAG Lead Pharmacist	Superseded	Due for review July 2009
2	Sept 2009	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, NNUH / Fiona Marshall TAG Lead Pharmacist	Superseded	No changes from July 2007. Supported by the TAG.
3	Nov 2012	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, NNUH / Fiona Marshall TAG Lead Pharmacist	Superseded	No changes from September 2009. Approved by the NNUH D&TC September 2012. Supported by the TAG in November 2012.

				Approved by the N&W Drugs & Therapeutics Commissioning Group November 2012
4	Nov 2014	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, NNUH / Fiona Marshall TAG Lead Pharmacist	Superseded	Updated into current TAG template format. Clinical content for review by author October 2014. No changes recommended by the authors. Advice to contact the specialist if the GP encounters any problems related to this treatment to be added to the document. Otherwise supported by the TAG November 2014
5.0	Sept 2016	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, Karen Blair, Specialist Nurse, NNUH / Fiona Marshall TAG Lead Pharmacist, NEL CSU Anglia	Draft	Updated into current TAG template format. Request to author for review.
5.1	Jan 2017	Dr Nandu Thalange, Consultant Paediatric Endocrinologist, Karen Blair, Specialist Nurse, NNUH / Fiona Marshall TAG Lead Pharmacist, NEL CSU Anglia	Current	Updated in line with manufacturer's SPCs and updated author, administration, prescribing and monitoring responsibilities, and contact info provided by the NNUH.
6	Dec 2018	TBC, / Fiona Marshall TAG Lead Pharmacist, NEL CSU Anglia	Draft	Logos updated. Reviewed and updated in line with current SPCs – hyperlinks added. Authors to be reviewed and confirmed.
6.1	Dec 2018/Jan 2019	Dr Vipan Datta. Dr Emma Webb, Dr Ravi Alanoor, Jenny Lind Children's Department, Norfolk & Norwich University Hospital / Fiona Marshall TAG Lead Pharmacist, AGEM CSU	Draft	Dr Emma Webb added, Nandu Thalange and Karen Blair removed – contact details added. "cases where puberty needs to be delayed in order to maximise growth potential in growth hormone deficient children" added to criteria for use at Dr Datta's request in line with BSPED shared care guidance on Use of Gonadotrophin Releasing Hormone (GnRH) Agonists - Triptorelin (July 2015). Clarification that 3 x monthly injections are given by hospital

				as part of initiation of treatment. Supported by
7.0	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
8.0	Dec 2022	Authors as above	Final	Reviewed by authors, updated to new template, ratified by Planned Care and Medicines Management Working Group
8.1	March 2023	Jen Carroll, TAG Lead Technician	Final	Amendment to dose initiation and maintenance
8.2	March 2023	Jen Carroll, TAG Lead Technician	Final	Action of minor amendments (terminology) from Karen Blair (Paediatric Endocrine Nurse), NNUH