THE SHEFFIELD AREA PRESCRIBING GROUP

Shared Care Protocol

For

Triptorelin (Gonapeptyl depot and Decapeptyl SR) for the treatment of Central Precocious Puberty in Children

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Date approved: February 2020

Review Date: February 2025

Shared Care Protocol for Triptorelin for the treatment of Central Precocious Puberty in Children

Statement of Purpose

This shared care protocol has been written to enable the continuation of care by primary care clinicians of patients initiated on TRIPTORELIN by the specialist paediatric endocrinologists at Sheffield Children's NHS Foundation Trust. Primary care will only be requested to take over prescribing of triptorelin within its licensed indication unless specifically detailed otherwise below.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. If a GP is invited by a specialist to participate in a shared care arrangement and is not confident to undertake these roles, then he or she is under no obligation to do so, but should discuss this with the specialist as soon as possible.

Indication

Treatment of confirmed central precocious puberty (CPP) in girls under 8 years and boys under 9 years.

Triptorelin is a gonadotrophin releasing hormone (GnRH) agonist. This inhibits gonadotroph activity in children with precocious puberty leading to a suppression of oestradiol in girls and testosterone in boys. Triptorelin is currently the only licensed GnRH agonist for use in precocious puberty.

The British Society for Paediatric Endocrinology and Diabetes shared care guidelines can be found at: https://www.bsped.org.uk/media/1695/gnrh-agonists-shared-care-guidelines-final-version-november-2019.pdf

Selection of patients

The duration of the treatment is dependent on the age at which the diagnosis of precocious puberty is made. GnRH agonists are usually continued until the patient reaches 10-11 years of age (when bone maturation is consistent with age 12 years in girls or 13-14 years in boys). The time at which triptorelin is discontinued is patient specific and decided following consultation with the specialist and family.

Dosage

Triptorelin as acetate (*Gonapeptyl Depot*® 3.75mg) licensed for use in girls under 9 years, boys under 10 years of age given by subcutaneous or intramuscular injection:

Body weight	<20kg – 1.875mg every 4 weeks
Body weight	20kg - 30kg – 2.5mg every 4 weeks
Body weight	>30kg – 3.75mg every 4 weeks

The frequency may be increased to every 3 weeks if clinically necessary.

Triptorelin as pamoate (*Decapeptyl SR® 11.25mg*) licensed for use in girls under 8 and boys under 10 years of age given by intramuscular injection:

11.25mg every 10 -12 weeks. The dose will then be adjusted by pubertal staging by the consultant Endocrinologist. Usual dosing interval is 6 -10 weeks.

Decapeptyl SR® is licensed for precocious puberty to be administered every 3 months. This interval may be reduced by the specialist to prevent pubertal breakthrough, more frequent administration is off label.

**** It is essential to keep the patient on the prescribed interval to prevent pubertal breakthrough ****

Contra-indications

Hypersensitivity to the drug or any excipients. Pregnancy and breastfeeding. Undiagnosed vaginal bleeding

Side –effects

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

Hypersensitivity reactions, injection site reactions (redness, inflammation and/or pain), headache, hot flushes, weight gain, increased blood pressure, blurred or abnormal vision, gastrointestinal disorders including abdominal pain or discomfort and vomiting, nose bleeds, feeling unwell, muscle pain, mood disorders, nervousness and skin rashes.
Girls **commonly** (less than 1 in 10 patients treated) may get some vaginal bleeding in the first month of treatment.

Interactions

The details below are not a complete list and the BNF and the SPC remain authoritative
No formal drug-drug interaction studies have been performed.
Drugs which raise prolactin levels should not be prescribed concomitantly as they reduce the level of GnRH receptors in the pituitary.
When co-administered with drugs affecting pituitary secretion of gonadotropins, caution should be exercised and it is recommended that the patient's hormonal status be supervised by the specialist.
Since androgen deprivation treatment may prolong the QT interval, the concomitant use of with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes should be carefully evaluated

Monitoring

Growth velocity and sexual stage: every 6 months by the endocrinology team at Sheffield Children's Hospital. If this progresses the endocrinology team may increase the frequency of injections, consider changing to another preparation or stopping therapy.

Treatment will be stopped by the Consultant Endocrinologist after assessment of the patient and discussion with the patient and family. Treatment should be stopped around the physiological age of puberty.

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 triptorelin in appropriate patients
- To monitor the patient as described above
- To prescribe the first 3 months supply or until the patient is stable
- 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, including the length of treatment
- To provide GP with written information regarding the diagnosis and indication for GnRH therapy along with dosage, preparation used and frequency of injections
- To review the patient in clinic every 6 months
- 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 triptorelin

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 guideline

- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To facilitate the administration of subsequent injections at the surgery as appropriate. The injections should not be delayed beyond the recommended time period for any reason, but can be brought forward by a few days if needed for practical or logistical reasons.
  To monitor patient's overall health and well-being.
- 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 or more frequent if required
- In the event that the GP is not able to prescribe, or where shared care 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 a secure method on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist issued Drugs on Clinical Practice Systems

Patient/Parent Responsibilities

- 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**.**

Re-Referral guidelines

The patient will remain under the care of the endocrinology team at Sheffield Children's Hospital for the duration of their treatment. Reasons to contact the specialist team include:

- Advancement of pubertal symptoms
- Increased vaginal bleeding in female patients
- Suspicion of non-compliance of treatment (e.g. prescriptions not being requested / patients not attending for injections)

Financial implications

Gonapeptyl Depot 3.75mg: £81.69 per pre-filled syringe
Decapeptyl SR 11.25mg: £207.00 per injection

Ordering information

Available from pharmacy wholesalers

Support, education and information

Paediatric Endocrinolgy Team at Sheffield Children's Hospital:
Dr N P Wright, Consultant Paediatric Endocrinologist
Professor P J Dimitri, Consultant Paediatric Endocrinologist
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Child Growth Foundation: www.childgrowthfoundation.org

References

BNFc 2019-2020
SPC Gonapeptyl Depot 3.75mg
SPC Decapeptyl SR 11.25mg
BSPED Shared Care Guideline: Use of Gonadotrophin Releasing Hormone agonists – Triptorelin (2019)