Shared Care Guideline

Triptorelin

(Gonapeptyl Depot 3.75mg) 4 weekly administration/ (Decapeptyl SR 11.25mg) 12 weekly administration – Precocious Puberty

Executive Summary

- **Indication** - Triptorelin is a gonadorelin analogue used in the treatment of confirmed central precocious puberty.
- **Patient treatment group -** The hospital paediatric endocrinology team will have confirmed a diagnosis of precocious puberty.
- **Dosage adjustments to be carried out, where agreed -** Once the initial course of treatment (up to day 56) has been administered in hospital, the GP will be advised in writing of the dose and also any subsequent changes in dosage.
- **Monitoring:**

  GP - The GP will:
  - Prescribe the drug treatment as described.
  - Report any adverse events to the paediatric endocrinology team where appropriate.

  Hospital - The hospital will ensure:
  - A letter is sent to the GP after each paediatric endocrinology clinic attendance ensuring current dose, most recent blood results and frequency of monitoring.
  - Growth and pubertal assessment will be monitored regularly at clinic appointments.
  - Evaluation will take place of any reported adverse effects by GP or patient.
- **Criteria for treatment continuation and definition of treatment failure -** Treatment success will be monitored at clinic appointments, checking height and weight and using the Tanner puberty staging method bone age assessment and an LHRH test as necessary.
- **What to do in the event of treatment failure or adverse monitoring results -** Should the suppressive effect be insufficient, Gonapeptyl 3.75mg Depot injections may be given every 3 weeks, Decapeptyl SR 11.25mg may be given every 10 weeks. The paediatric endocrinology team will advise the GP in writing.
- **Discontinuation of drug if indicated -** The hospital team will be responsible for discontinuation of the drug.
- **The responsibilities of the hospital specialist, GP and patient for this Shared Care Guideline can be found within this document here.**

Sharing of care depends on communication between the specialist, GP and the patient or their parent/ carer. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. The doctor/ healthcare professional who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

1. Scope

Trust-wide and general practice for paediatric patients up to 16 years of age.

2. Aim

Sharing of care assumes communication between the specialist, GP and the patient. The intention to shared care should be explained to and accepted by the patient. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

3. Introduction

Triptorelin as Gonapeptyl Depot 3.75mg or Decapeptyl SR 11.25mg is a gonadorelin analogue used in the treatment of confirmed central precocious puberty and will be initiated by the paediatric endocrinology team following the results of relevant investigations.

4. Abbreviations

GP	general practitioner
IM	intramuscular
LHRH	luteinising hormone releasing hormone
GnRH	gonadotophin-releasing hormone

5. Dose and Administration

- At the beginning of treatment the appropriate dose for weight of Gonapeptyl 3.75mg Depot injection will be given IM or subcutaneously on days 0, 14, 28 and 56.
- This initial course of treatment will be given at the hospital by the clinical nurse specialist at the paediatric endocrinology unit.
- Immediately prior to the 4th Gonapeptyl 3.75mg Depot injection on day 56, a repeat endocrine blood test to check LH. FSH will be performed by the paediatric endocrine team to ensure stimulus for puberty has been suppressed.
- If treatment started with Decapeptyl SR 11.25mg every 12 weeks, this will be initiated by the clinical nurse specialist at the paediatric endocrinology unit.
- Immediately prior to the next injection at 12 weeks, a repeat endocrine blood test to check LH, FSH will be performed by the paediatric endocrine team to ensure stimulus for puberty has been suppressed.
- Thereafter, Gonapeptyl 3.75mg Depot injections are administered every 28 days or Decapeptyl SR 11.25mg injections are administered every 12 weeks and both can be administered by paediatric community nursing teams or GP practice nurses
- Once suppression of puberty has been achieved. Upon consultation with endocrine specialist and was initiated on Gonapeptyl 3.75mg Depot injection, some patients may choose to swap to Decapeptyl SR 11.25mg which can be administered every 12 weeks
- If the injection cannot be given on the date it is due, it should be given early rather than late.
- Should the suppressive effect be insufficient, Gonapeptyl 3.75mg Depot injections may be given every 3 weeks; Decapeptyl SR 11.25mg may be administered every 10 weeks. The paediatric endocrinology team will advise the GP in writing in these cases.

- Gonapeptyl 3.75mg Depot injection dosing should be based on body weight. Children weighing less than 20 kg should receive 1.875 mg (half dose), children between 20 and 30 kg receive 2.5 mg (2/3 dose), and children more than 30 kg body weight should receive 3.75 mg (full dose). Decapaptyl SR 11.25mg is set dose of 11.25mg The GP will be advised in writing of the appropriate dose and also if any changes in dosing are required.
- The injection sites should be varied each time.
- Treatment is continued and discontinued as per clinical requirements/ needs as advised by specialist

6. Adverse Effects

Common (≥ 1 in 100 and < 1 in 10):

- Mood changes, depression

Uncommon (≥ 1 in 1000 and < 1 in 100):

- Anaphylaxis
- Nausea
- Vomiting
- Vaginal bleeding, vaginal discharge

Incidence unknown:

- Hypersensitivity reactions
- Headache
- Vision blurred
- Visual impairment
- Hot flushes
- Epistaxis
- Abdominal discomfort
- Rash
- Myalgia
- Malaise

7. Cautions

- When Triptorelin is co-administered with drugs affecting pituitary secretion of gonadotrophins, caution should be taken and the patient's hormonal status should be supervised.
- The chronological age at the beginning of therapy should be under 9 years of age in girls.
- After finalising therapy, development of puberty characteristics will occur. Information regarding future fertility is still limited. In most girls menses will start on average one year after ending therapy, in most cases these are regular.
- Allergic and anaphylactic reactions have been reported in children. Patients should be monitored for signs of allergic or anaphylactic reaction.

8. Contraindications

- Known hypersensitivity to Triptorelinpoly-d,l lactide coglycolide, dextran or to any of the excipients.
- Known hypersensitivity to gonadotrophin-releasing hormone (GnRH) or any other GnRH analogue.

9. Interactions

- When triptorelin is co-administered with drugs affecting pituitary secretion of gonadotrophins caution should be given and it is recommended that the patient's hormonal status should be supervised.

Further information about dose and administration, adverse affects, cautions, contraindications and interactions can be found in the Summary of Product Characteristics.
Gonapeptyl Depot 3.75 mg
Decapeptyl SR 11.25mg

10. Monitoring Standards & Actions to take in the event of abnormal test results/ symptoms

The paediatric endocrinology team will supervise treatment and perform all necessary monitoring which includes:

- Height
- Weight
- Assessment of pubertal development using the Tanner puberty staging method bone age assessment
- endocrine blood tests - including LHRH test as required.

11. Shared Care Responsibilities

a. Hospital specialist:

- The decision to start Gonapeptyl Depot 3.75mg/ Decapaptyl SR 11.25mg will be made by the paediatric endocrinology team. A copy of the shared care guidelines will be sent with a letter to the GP requesting shared care for the patient. If the GP has any queries about the prescribing of Gonapeptyl Depot 3.75mg/ Decapaptly SR 11.25mg, they should contact the relevant hospital specialist as soon as possible.
- Routine paediatric endocrine clinic follow-up will take place on a regular basis.
- A letter will be sent to the GP after each paediatric endocrinology clinic attendance to confirm current dose, most recent blood results and frequency of monitoring.
- Growth and pubertal assessment will be monitored regularly at clinic appointments.
- Evaluation will take place of any reported adverse effects by GP or patient.
- GP will be advised on review, duration or discontinuation of treatment where necessary.
- GP will be informed of patients who do not attend clinic appointments.
- GP will be assured that backup advice is available at all times.
- To provide any advice to the patient/carer when requested.

b. General practitioner:

- Agreement to shared care guideline by the GP.
- Prescribe the drug treatment as described.
- Report any adverse events to the paediatric endocrinology team where appropriate.
- Request advice from the hospital specialist when necessary.

c. Patient or parent/ carer:

- Report to the hospital specialist or GP if they do not have a clear understanding of their treatment.
- Patients must not exceed the recommended dose.
- Patients must attend their scheduled clinic and blood test appointments (where relevant).
- Must inform other clinical staff that they are receiving treatment.
- Report any adverse effects to the hospital specialist or GP.

12. Contact numbers for advice and support

Cambridge University Hospitals NHS Foundation Trust

Specialist	Post	Telephone
Dr Rachel Williams	Consultant - Paediatric Endocrinology & Diabetes	01223 274311
Dr Ajay Thankamony	Consultant - Paediatric Endocrinology & Diabetes	01223 274311
Dr Emile Hendricks	Consultant - Paediatric Endocrinology & Diabetes	01223 274311
Dr Sandra Walton-Betancourth	Consultant - Paediatric Endocrinology & Diabetes	01223 274311
Dr Loredana Marcovecchio	Consultant - Paediatric Endocrinology & Diabetes	01223 274311
Professor Ken Ong	Professor and Consultant in Paediatric Endocrinology	01223 274311
Specialist Registrar – paediatric endocrinology	On Call SpR. for Endocrinology	01223 217495
Karis Reyes & Susan Sparrow	Clinical Nurse Specialists, paediatric endocrinology	01223 217496
Pharmacy Medicines Information		01223 586862 / 348745

North West Anglia NHS Foundation Trust

Specialist	Post	Telephone
Vijith Puthi	Consultant paediatrician	01733 673087

13. Monitoring compliance with and the effectiveness of this document

The paediatric endocrinology team will continue to monitor feedback from GPs with regard to the guideline and the use of the drug on a regular basis (normally yearly) and make changes as appropriate.

Equality and diversity statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

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Document management

Ratification Process	**Details**
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The information contained in this guideline is issued on the understanding that it is accurate based on the resources at the time of issue. For further information please refer to the most recent Summary of Product Characteristics.
Gonapeptyl Depot 3.75 mg
Decapeptyl SR 11.25mg

Triptorelin (Gonapeptyl Depot 3.75mg) 4 weekly administration/ (Decapeptyl SR 11.25mg) 12 weekly administration – Precocious Puberty – Template Letter

{GP ADDRESS}

Dear Dr,

{PATIENT DETAILS}

{Insert patient name} is under the care of the Paediatric Endocrine Team at Addenbrooke's Hospital for assessment of early pubertal development.

Treatment with 4 weekly Gonapeptyl (triptorelin acetate) Depot 3.75mg injections was initiated and most recent blood test shows that the stimulus for puberty has now been suppressed.

OR

Treatment with 4 weekly Gonapeptyl (triptorelin acetate) Depot 3.75mg injections was initiated and subsequently changed to an equivalent 12 weekly preparation, Decapeptyl (triptorelin pamoate)11.25mg SR.

OR

Treatment was initiated with Decapetyl (triptorelin pamoate)11.25mg SR and most recent blood test shows that the stimulus for puberty has now been suppressed.

We have arranged for ***{Insert patient name}*** next injection to be given at the Weston Centre at the same time as he/her follow up appointment on ***{Insert date}.***
Following this, it would be easier for the family to have these given by a practice nurse at their local GP surgery so I am therefore writing to ask you to participate in the shared care for this patient.

This medication and indication has been accepted as suitable for shared care by the Cambridgeshire and Peterborough Integrated Care System. I agree to the secondary care responsibilities set out in the shared care agreement for this medication. I am therefore requesting your agreement to share the care of this patient.

Medication name:	**Decapeptyl (triptorelin pamoate) SR 11.25mg injections** **OR** **Gonapeptyl (triptorelin acetate) Depot 3.75mg injection**
Current dose:	{insert dose}
Date medication started:	{Insert date}

Date after which GP to start prescribing: {Insert date}[1]

{Insert if applicable - Last bloods were taken on {Insert date} and these show {Insert blood test details} within the normal range. The latest results are attached below.}

{Insert if applicable - The dose has been titrated and is stable.}

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted and the need for monitoring, how monitoring will be arranged, and the roles of the consultant/nurse specialist, GP and the patient in shared care.
I confirm the patient has understood and is satisfied with this shared care arrangement.
Yours sincerely

{Consultant name}

[1]This should be the date when the last prescription was issued. It is expected that patients will request a repeat prescription sometime after this date.