SHARED CARE PRESCRIBING GUIDELINE
Triptorelin (Gonapeptyl Depot 3.75 mg™, Decapeptyl SR 11.25 mg™) for precocious puberty

Surrey PCT's Medicines Management Committee classification: Amber

N.B. The eligibility criteria included here apply to new patients commencing treatment under this guideline & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

NOTES to the GP

Amber drugs: Prescribing to be initiated by a hospital specialist (or if appropriate by a GP with specialist interest) but with the potential to transfer to primary care. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs.

The questions below will help you confirm this:
- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your PCT pharmacist will assist you in making decisions about shared care.

It would not normally be expected that a GP would decline to share prescribing on the basis of cost.

The patient’s best interests are always paramount

The GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant.
**Information** (this page should include general information relevant to the specific drug / indication. It should include information on the dose of the drug for the indication, cautions, contraindications, common side effects and interactions to look out for. This section should have input from a specialist consultant in the field.)

This information sheet does not replace the SPC, which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

<table>
<thead>
<tr>
<th>Indication(s):</th>
<th>Treatment of confirmed central precocious or early puberty (girls under 9 years, boys under 10 years).</th>
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<tbody>
<tr>
<td></td>
<td>Central precocious puberty is defined as premature activation of the hypothalamic-pituitary-gonadal axis with presence of secondary sexual characteristics in any girl less than 9 years or boy less than 10 years.</td>
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</table>

**Place in Therapy:**

Triptorelin is the only GnRH analogue licensed in the UK for central precocious puberty in children. It is used where puberty needs to be delayed in order to maximise growth potential, e.g. growth hormone deficient children following cranial irradiation. In case of an allergic reaction to Triptorelin, alternative products such as Leuprorelin and rarely Goserelin will be used. **Leuprorelin and Goserelin are not licensed for precocious puberty and will be prescribed by the hospital (i.e. not under shared care arrangements).** In cases where puberty is beginning early and is felt by the family and consultant to be adversely affecting an individual psychologically, Triptorelin may also be considered.

**Therapeutic Summary:**

In children suffering from central precocious puberty, Triptorelin treatment leads to a suppression of the secretion of gonadotrophins, oestradiol and testosterone to prepubertal levels. This results in arrest or even regression of pubertal signs and an increase in adult height prediction in CPP patients. The effect is reversible on discontinuation of therapy.

**Dose:**

**Route of Administration:**

**Gonapeptyl Depot 3.75 mg**

It is important that the injection of the sustained release form be performed strictly in accordance with the instructions in the Summary of Product Characteristics.

**Initiation by hospital:** At least 3 doses will be given by the hospital on days 0, 14 and 28 days.

**Maintenance** (under shared care arrangement): single subcutaneous (e.g. into skin of abdomen, buttock or thigh) or deep intramuscular injection every 28 days at a dose as instructed by the hospital in accordance to child’s weight:

<table>
<thead>
<tr>
<th>Gonapeptyl Depot</th>
<th>Decapeptyl SR</th>
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<tbody>
<tr>
<td>&lt;20 kg: 1.875 mg (half vial)</td>
<td>5.625 mg</td>
</tr>
<tr>
<td>20 – 30 kg: 2.5 mg (2/3 vial)</td>
<td>7.5 mg</td>
</tr>
<tr>
<td>&gt; 30 kg: 3.75 mg (full vial)</td>
<td>11.25 mg</td>
</tr>
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</table>

Should the effect be insufficient, the injection may be given every 3 weeks or the dosage altered after guidance from the hospital staff. **The injection site should be changed each time.**

**Decapeptyl SR 11.25 mg**

Once efficacy of Gonapeptyl Depot has been ascertained clinically and through blood tests, Decapeptyl SR may be substituted at 3 times the interval on advice from the hospital team by IM injection.

**Duration of Treatment:**

Treatment should be stopped if a bone maturation of older than 12 years in girls and older than 13 years in boys has been achieved. This will be assessed by the consultant paediatrician in general when the child is mature enough and ready for puberty to develop as measured by psychological and growth assessment. This will vary with each child but will tend to be around 11 years of age. Parents/patients and endocrinologist make the decision jointly.
Summary of Adverse Effects:
(See summary of product characteristics (SPC) for a comprehensive list)

In the initial stages of therapy (after first injection), a transient rise in levels of gonadotrophins and hence sex steroids may occur. This is due to an initial stimulation of GnRH receptors before they are blocked. In females with advanced precocious puberty, vaginal bleeding may occur (parents are warned of this). Such patients can be treated with an anti-androgen drug such as Cyproterone starting 3 days before and continuing for 2 weeks after the commencement of GnRH analogue therapy. This has been reported to prevent the sequelae of an initial rise in sex steroids but is not necessary in every patient.

The paediatrician will prescribe the full course of the anti-androgen therapy when the decision to initiate Triptorelin therapy is made. GPs will not be required to prescribe this.

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Frequency</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruising and rashes around the injection site</td>
<td>Frequent</td>
<td>It is advisable to vary the injection site periodically</td>
</tr>
<tr>
<td>Local site reactions, systemic allergic and anaphylactic reactions</td>
<td>More common in children</td>
<td>Stop injections and refer back to consultant</td>
</tr>
<tr>
<td>Peripheral oedema, fatigue and nausea and vomiting</td>
<td>Uncommon (1 – 10/1000)</td>
<td>Symptomatic management – refer to consultant if severe</td>
</tr>
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</table>

Monitoring Requirements:
- 

Clinically Relevant Drug Interactions:
Oestrogen containing medicinal products should not be used during treatment with Gonapeptyl Depot or Decapeptyl SR.

Practical Issues:
Triptorelin (Gonapeptyl Depot®):
- Store at 2 – 9°C (in a refrigerator)
- For single use only and any unused suspension should be discarded.

Since successful treatment depends upon correct preparation of the suspension, it is important that the injection be performed strictly in accordance with the instructions in the Summary of Product Characteristics.

Key References:
1. SPC Gonapeptyl Depot Ferring Pharmaceuticals 2004
4. SPC Decapeptyl SR Ipsen
Product Presentation and Cost

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
<th>Available strengths</th>
<th>Cost of therapy per injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gonapeptyl Depot®</td>
<td>Ferring</td>
<td>3.75 mg prefilled syringe</td>
<td>£85.00 (~ £3.03 /day)</td>
</tr>
<tr>
<td>Decapeptyl SR®</td>
<td>Ispen</td>
<td>15-mg vial (contains overage to allow 11.25 mg/administration)</td>
<td>£207.00 (~£2.46/day)</td>
</tr>
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Criteria for Use

1. CIRCUMSTANCES WHERE SHARED CARE IS APPROPRIATE

- Prescribing responsibility will only be transferred when the consultant and the GP are in agreement that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case and the hospital will continue to provide prescriptions until successful transfer of responsibilities as outlined below.
- The hospital will provide the patient with a minimum initial supply of 4 weeks therapy.

2. RESPONSIBILITIES and ROLES

Specialist responsibilities

- Discuss treatment options with the patient/parent and identify appropriate patient to receive Triptorelin.
- Initiate Triptorelin therapy (at least first 3 doses).
- Prescribe full course of anti-androgen therapy when required on initiation of Triptorelin therapy.
- Seek the cooperation of the GP in undertaking shared care of the patient, in accordance with these guidelines, in the referral letter or by telephone.
- Provide health professionals administering Triptorelin with appropriate information leaflets.
- Provide the patient with appropriate patient information leaflets.
- Regularly review patient’s pubertal development, growth and response to treatment at 3 to 6 monthly intervals.
- Advise GP as to continued justification for Triptorelin therapy after each review.
- Explain to the patient / carer their roles

General Practitioner responsibilities

- Subsequent prescribing of Triptorelin at the dose recommended.
- Monitor the patient’s overall health status.
- Report any adverse events or other relevant information or concerns to the consultant.
- Cooperate with Endocrine Nurse Specialist / Paediatric Outpatient Sister / Community Paediatric Team in arranging appropriate administration of Triptorelin in primary care (either by Community Paediatric Team or GP Practice) and ensure that staff administering Triptorelin has access to support and/or training from Endocrine Nurse Specialist.

Monitoring requirements and appropriate dose adjustments (if relevant to specific drug)

Monitoring will be undertaken by the paediatric team including:

- 4 – 6 monthly height, weight and pubertal staging
- Yearly bone age assessment
- Hormone measurements prior to drug administration if clinically indicated (in this case the drug will be administered by the hospital and not under shared care arrangements)

Dose will be as recommended by the paediatric team.
### Patient's / Carer's role

1. Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with Triptorelin.
3. Tell the specialist or GP of any other medication being taken, including over-the-counter products.
4. Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP.

### BACK-UP ADVICE AND SUPPORT

<table>
<thead>
<tr>
<th>Hospital contacts: (Royal Surrey County Hospital)</th>
<th>Out of hours contacts &amp; procedures:</th>
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<tbody>
<tr>
<td>Paediatric Consultant: Dr M R Ryalls</td>
<td>Dr Mike Ryalls (Consultant Paediatrician with special interest in growth and endocrinology) page via switchboard on 01483 571122</td>
</tr>
<tr>
<td>Paediatric Pharmacist: Alison Marshall</td>
<td>On call pharmacist via RSCH switchboard</td>
</tr>
<tr>
<td>Nurse Specialist: Pippa Sherry</td>
<td>On call paediatric registrar via RSCH switchboard</td>
</tr>
<tr>
<td>(the referral letter will indicate named consultant)</td>
<td></td>
</tr>
<tr>
<td>Tel: 01483 464182</td>
<td></td>
</tr>
<tr>
<td>Fax: 01483 450742</td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="mailto:mryalls@royalsurrey.nhs.uk">mryalls@royalsurrey.nhs.uk</a></td>
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</tbody>
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### Specialist support / resources available to GP including patient information:

- Child Growth Foundation information leaflet for families of children with precocious puberty
- Information leaflet for professionals administering LH-RH injections

### AUDIT / SURVEY

(to be carried out by specialist clinic)
Agreement for transfer of prescribing to GP

Patient details / addressograph:

Name……………………………………..
Address……………………………………..
DOB……………………………………..
Hospital No………………………………

Drug name and dose:
The following tests, investigations have been carried out:
List any relevant tests:

Date initiated:………………………………

At the last patient review the drug appeared to be effectively controlling symptoms/ providing benefit:
Yes / No

The patients has now been stabilised on a dose of: ……………………………………………

I will arrange to review this patient regularly. Date of next clinic appointment:…………………………

Consultant:
Address:
Contact Number

GP:
Address:
Contact Number

Main Carer:
Contact Number:

Key worker if appropriate:
Contact Number:

Agreement to shared care, to be signed by GP and Consultant.

Consultant Signature:
………………………………………………..
Date:
………………………………………………..

GP Signature:
………………………………………………..
Date:
………………………………………………..

If shared care is agreed and GP has signed above please return a copy of this page to the requesting consultant or alternatively fax to:
Acute Trust please insert appropriate Fax Number: