**DRUG:**

<table>
<thead>
<tr>
<th>LONG ACTING SOMATOSTATIN ANALOGUES in Acromegaly (Adults)</th>
</tr>
</thead>
</table>

| OCTREOTIDE (Sandostatin LAR) |
| LANREOTIDE (Somatuline LA, Somatuline Autogel) |

### Introduction:

**Indications:**
Symptomatic control and reduction of growth hormone and insulin like growth factor-1 (IGF-1) plasma levels in patients with acromegaly inadequately controlled by surgery or radiotherapy.

**Licensing Information:**
Somatulin Autogel, Somatulin LA and Sandostatin LAR are licensed for the treatment of individuals with acromegaly when the circulating levels of Growth Hormone and/or Insulin-like Growth Factor-1 remain abnormal after surgery and/or radiotherapy (Somatulin Autogel is also licensed for patients who otherwise require medical treatment).

Sandostatin LAR is also licensed for the interim period until radiotherapy becomes fully effective and in short term treatment (3-12 months) prior to pituitary surgery.

### Formulations (used locally):
- Sandostatin 1mL ampoule of 50 microgram/mL (for initial dose titration – prescribed by secondary care only)
- Sandostatin LAR depot injection (microsphere powder for aqueous suspension) 10mg, 20mg and 30 mg vial supplied with 2.5ml diluent-filled syringe
- Somatuline LA 30mg vial with vehicle
- Somatuline Autogel 60mg, 90mg, 120mg prefilled syringe

### Dosage & administration in acromegaly:
Patients will typically have initially received treatment from secondary care with subcutaneous octreotide 100 to 200 micrograms three times a day (max 1500mg per day) as subcutaneous injection. They will then be converted to a long acting preparation of octreotide (Sandostatin LAR) or lanreotide (Somatuline LA or Autogel) by the specialist as shared care. Choice of long acting preparation is based on Consultant preference/experience.

For all drugs/formulations the injection site should be alternated between the right and left sides.

**Sandostatin LAR -** By deep intragluteal injection. Treatment is usually...
started with 20mg every 4 weeks and then will be titrated by the specialist according to response Max 30mg every 4 weeks.

**Somatuline LA** – By intramuscular injections into the buttock. Treatment is usually started with 30mg every 14 days and then will be titrated by the specialist according to response up to a maximum frequency of every 7 days.

**Somatuline Autogel** – By deep subcutaneous injection into the superior, external quadrant of the buttock. Patients who self-administer should inject in the upper, outer thigh. Treatment is usually started with 60mg every 28 days and then will be titrated by the specialist according to response.

### Contraindications & Cautions:

- Growth hormone secreting pituitary tumours can expand with treatment and patients should be monitored for signs of tumour expansion (e.g. visual field defects) – see under monitoring
- In hepatic impairment dose adjustment may be required.

### Contraindications

- Pregnancy and breast feeding- manufacturer advises avoid. Note women with acromegaly may have fertility restored on treatment and should therefore use adequate contraception.
- Hypersensitivity to octreotide/lanreotide or any of the excipients contained in the injection.

### Interactions:

**Antidiabetic agents**: the requirements for insulin, metformin, repaglinide and sulphonylureas may be reduced. The effect is likely to be more significant in type 1 diabetic patients treated with insulin

**Ciclosporin**: there may be a marked reduction in ciclosporin levels. Monitor ciclosporin levels

**Bromocriptine**: the bioavailability of bromocriptine may be modestly increased

**Beta blockers, calcium channel blockers and agents used to control fluid and electrolytes** – patients taking these drugs should have their heart rate monitored when starting or changing the dose of octreotide/lanreotide (as bradycardia and less commonly tachycardia may occur)

**Drugs metabolised by cytochrome P450 (eg carbamazepine, digoxin, warfarin)**: The SPC states that theoretically may be increased levels of these agents when administered with octreotide/lanreotide. Be vigilant for symptoms and potential need to reduce doses.

For full list see BNF or SPC at [www.medicines.org.uk/EMC](http://www.medicines.org.uk/EMC)
### Adverse Effects:

**Gastro-intestinal disturbances** are the most common side effects including anorexia, nausea, vomiting, abdominal pain, bloating, flatulence and diarrhoea. If symptoms persist, liaise with hospital specialist who will advise on management.

**Steatorrhoea** – refer patients with symptoms back to the hospital specialist to consider starting pancreatic enzyme supplements.

**Gall stones** have been reported with long term treatment in 15-30% of patients. Abrupt withdrawal of subcutaneous treatment is associated with biliary colic and pancreatitis.

**Dermatological reactions** - Pain and irritation can be experienced at injection sites. Injection sites should be alternated between the right and left side. Pruritus, rash and alopecia are also common.

**Glucose control** - Post prandial glucose tolerance may be impaired and rarely persistent hyperglycaemia with long term use. Hypoglycaemia has also been reported. The patients diabetes control will be monitored by the hospital and treatment adjusted as necessary.

**Cardiac** – Bradycardia or uncommonly tachycardia.

**Thyroid dysfunction** – usually hypothyroidism. If symptoms present refer back to specialist or check thyroid function tests and refer back to specialist.

**Hepatic dysfunction** – refer back to specialist if changes in liver function are identified by primary care.

**Miscellaneous** – headache, dizziness and dyspnoea.

For full list see BNF or SPC at [www.medicines.org.uk/EMC](http://www.medicines.org.uk/EMC)

### Responsibilities of the specialist initiating treatment:

**General:**
- To assess the suitability of the patient for treatment.
- To ensure that the patient/carer has received counselling and understands the therapy, its benefits, limitations, continued monitoring (where applicable), adverse effects, and is aware of actions to take if adverse effects are suspected.
- Teach injection technique for initial subcutaneous injections of s/c short acting Sandostatin and issue sharps container.
- Inform the GP of the information provided to the patient.
- To review the patient as agreed intervals and copy any relevant results to the GP.
- Carry out disease and drug monitoring as listed below.
- Formally hand over to GP by letter and patient informed - send a copy (either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care.
Prescribing:
- The specialist will prescribe short acting octreotide until the patient is ready to transfer to a long acting formulation of octreotide or lanreotide and the GP has agreed to participate in shared care. The GPs will be typically asked to take up the prescribing of octreotide or lanreotide approximately 3 months after initiating treatment with octreotide (short acting).

Disease & drug monitoring:
- Monitor bloods according to schedule:

<table>
<thead>
<tr>
<th>Test</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>IGF1</td>
<td>Baseline and at every clinic visit – which will be 3-12 monthly dependant upon patient and duration of treatment</td>
</tr>
<tr>
<td>HBA1c</td>
<td></td>
</tr>
<tr>
<td>Thyroid Function Tests</td>
<td></td>
</tr>
<tr>
<td>Routine BP,pulse,weight</td>
<td></td>
</tr>
<tr>
<td>Gall Bladder ultrasound</td>
<td>At baseline and annually</td>
</tr>
<tr>
<td>Luteinising Hormone</td>
<td></td>
</tr>
<tr>
<td>Follicle Stimulation</td>
<td></td>
</tr>
<tr>
<td>Hormone Prolactin</td>
<td></td>
</tr>
<tr>
<td>Cortisol</td>
<td></td>
</tr>
<tr>
<td>Vitamin B12</td>
<td></td>
</tr>
<tr>
<td>Thyroid Function Tests</td>
<td>At baseline and 1-2 yearly</td>
</tr>
<tr>
<td>Liver function tests</td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td></td>
</tr>
</tbody>
</table>

- Discuss shared care arrangement with patient.
- Support and advise GPs as required.
- Assess response to treatment and initiate any dose changes as clinically appropriate including discontinuation of treatment.

General and Prescribing:
- To reply to the request for shared care within 2 weeks of receipt of the Consultant letter.
- Prescribe as recommended by the specialist. The GPs will be typically asked to prescribe the first and subsequent doses of long acting octreotide/lanreotide.
- Arrange administration of octreotide/lanreotide, unless the patient or carer chooses to administer (only suitable for Sandostatin LAR and Somatuline Autogel). In all cases the manufacturer can be contacted to teach injection technique to health care professionals or patients/carers.
- Note - the manufacturer will issue sharps bins to a patient (or carer) if they choose to self inject.
- Notify Consultant if treatment with octreotide or lanreotide is discontinued.
- Ensure there are no drug interactions with any other medications initiated in primary care.
**Disease & drug monitoring:**
- Secondary care will normally carry out all routine blood monitoring as listed above unless agreed otherwise. GP to monitor for side effects, drug interactions etc.
- Refer back to the specialist if the patient’s condition deteriorates.
- Stop treatment on the advice of the specialist.
- Urgent drug discontinuation/ referral to specialist as clinically appropriate.
- Identify adverse effects if the patient presents with any signs and liaise with the hospital specialist where necessary. Report adverse effects to the specialist and where appropriate to the Commission on Human Medicines/MHRA (Yellow Card scheme).

| Monitoring | If patients present with worsening or uncontrolled acromegaly or symptoms typical of steatorrhoea, gallstones, glucose intolerance or visual problems or changes in liver function refer back to the specialist. Patients with underlying cardiac problems, especially those on beta blockers, calcium channel blockers and agents used to control fluid and electrolytes should have their heart rate monitored when changing the dose of octreotide/lanreotide (as bradycardia and less commonly tachycardia may occur) |

**Responsibilities of the Patient / Carer:**
- To undertake education in self injection or injection on behalf of patient if patient/carer wishes and is competent to inject. Training will be provided by secondary care for the initial s/c injections of short acting Sandostatin. Training for the long acting preparations will be organised by primary care and provided by the manufacturer (only suitable for Sandostatin LAR and Somatuline Autogel).
- To have an understanding of the use and storage of the medication and the side effects.
- To dispose of any needles and used injections in an appropriate sharps bin. The first container will be provided by secondary care and thereafter the manufacturer. Contact the local council to arrange for disposal of waste contained in sharps bin or alternatively return to the person who issued the sharps bin.
- To report any concerns or side effects to relevant medical professional including Consultant, GP, SpR or Endocrine Nurse
- To take adequate contraceptive measures - Note women with acromegaly may have fertility restored on treatment
- Attend appointments.

**Summary**
- To undertake education in self injection or injection on behalf of patient if patient/carer wishes and is competent to inject. Training will be provided by secondary care for the initial s/c injections of short acting Sandostatin. Training for the long acting preparations will be organised by primary care and provided by the manufacturer (only suitable for Sandostatin LAR and Somatuline Autogel).
- To have an understanding of the use and storage of the medication and the side effects.
- To dispose of any needles and used injections in an appropriate sharps bin. The first container will be provided by secondary care and thereafter the manufacturer. Contact the local council to arrange for disposal of waste contained in sharps bin or alternatively return to the person who issued the sharps bin.
- To report any concerns or side effects to relevant medical professional including Consultant, GP, SpR or Endocrine Nurse
- To take adequate contraceptive measures - Note women with acromegaly may have fertility restored on treatment
- Attend appointments.
adverse effects) and attend appointments including those for routine blood tests/investigations

Communication:

Specialist to GP:
- The specialist will inform the GP when they have initiated octreotide and when the patient is ready to transfer to a long acting formulation. They will also communicate any subsequent changes in treatment – standard clinic letter.
- Send a copy (either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care.
- Inform the GP of the information provided to the patient

GP to Specialist:
- To reply to the request for shared care within 2 weeks of receipt of the Consultant letter.
- Irrespective of whether you accept prescribing responsibility or not, you should inform the consultant of all relevant medical information regarding the patient and any changes to the patient’s medication regime irrespective of indication.
- Notify Consultant if treatment with octreotide/lanreotide is discontinued.

Contact names & details:
If you have any concerns regarding individual patients, see consultant letter for medical contact details or contact one of the following:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Location</th>
<th>Telephone / Bleep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Paul Jennings</td>
<td>Consultant in Diabetes and Endocrinology. York</td>
<td>01904 725604</td>
</tr>
<tr>
<td>Dr Jonathon Thow</td>
<td>Consultant in Diabetes and Endocrinology. York</td>
<td>01904 725604</td>
</tr>
<tr>
<td>Dr Vijay Jayagopal</td>
<td>Consultant in Diabetes and Endocrinology, York</td>
<td>01904 721175</td>
</tr>
<tr>
<td>Ottilia Buch</td>
<td>Specialist Endocrine Nurse</td>
<td>01904 726807</td>
</tr>
<tr>
<td>Scarborough Endocrinology secretaries</td>
<td>Dr David Humphriss, Dr Tadeusz Pawlak</td>
<td>01723 342036</td>
</tr>
</tbody>
</table>

Costs:

BNF March 2013
Sandostatin LAR  10mg=£427.13, 20mg=£705.50, 30mg=£903.13
Somatuline LA 30mg = £323.00
Somatuline Autogel 60mg =£551.00, 90mg=£736.00, 120mg= £937.00.

References:
   Sandostatin LAR SPC (last updated 23.4.13)
   Somatuline Autogel (last updated 25.10.11)
   Somatuline LA (last updated 19.10.10)
2. BNF March 2012
This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.

The original Microsoft Word file of this document is located on:
York Teaching Hospital NHS Foundation Trust Pharmacy Department X:\MEDICINES INFORMATION\Shared Care Guidelines\Approved Shared Care Guidelines\LONG ACTING SOMATOSTATIN ANALOGUES IN ACROMEGALY Shared Care Guideline V1.0

Shared Care Guidelines are available electronically via http://www.yorkandscarboroughformulary.nhs.uk/

Prepared by: Eunice Barry, Endocrine Specialist Nurse

Checked by: Katie Dore, Specialist Pharmacist, Jane Crewe
Diane Tomlinson (Pharmacist NY and Humber Commissioning Support Unit)

Version: 1.0

Date of Issue / Review: November 2013

Date for next Review: November 2015

Approved by: Drug & Therapeutics Committee November 2013