Please note: Adult specialist endocrinology services are not commissioned by CCGs. NHS England commissions treatments for pituitary and hypothalamic diseases, including acromegaly. Guidance should be provided to GPs by specialist services if requests are made to share care. This shared care guideline has been archived.

NORTH AND EAST DEVON HEALTH CARE COMMUNITY SHARED CARE PRESCRIBING GUIDELINE

http://www.devonpct.nhs.uk/Treatments/NE_Devon_Shared_Care_Guidelines.aspx#L

TREATMENT OF ACROMEGALY (PERSISTENT GH EXCESS) IN ADULTS SOMATOSTATIN ANALOGUES: OCTREOTIDE (SANDOSTATIN LAR®), LANREOTIDE (SOMATULINE LA®, SOMATULINE AUTOGEL®)

This shared care guideline sets out details for the sharing of care of patients with **ACROMEGALY** prescribed a **SOMATOSTATIN ANALOGUE**. These guidelines provide additional limited information necessary to aid in the treatment of patients with **ACROMEGALY.** As with all shared care guidelines they highlight significant prescribing issues but should be used in conjunction with the ABPI summary of product characteristics (SPC/Data sheet) and ***do not*** replace them.

INTRODUCTION/BACKGROUND INFORMATION

Acromegaly is a rare growth disorder (yearly incidence: 4-6 patients per million) characterised by a clinical syndrome resulting primarily from the effects of excess growth hormone and insulin-like growth factor-1 (IGF-1) on various organ systems. Acromegaly is almost always caused by a pituitary tumour.

There are three therapeutic options for confirmed acromegaly - surgery, radiotherapy and pharmacological therapy.

Octreotide and Lanreotide are pharmacological options. They appear to be effective in 55-70% of patients.

Somatostatin analogues exert potent inhibitory effects on the secretion of growth hormone and on various peptides of the gastroenteropancreatic endocrine system.

The drug formulations commonly used in acromegaly treatment are biodegradable polymer microspheres that contain and release the drug slowly over a 14-28 day period.

Dose adjustments are based on clinical symptoms, suppression of GH and normalisation of IGF-1.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

Treatment of patients with acromegaly who are adequately controlled on s/c treatment with octreotide: in whom surgery, radiotherapy or dopamine agonist treatment is inappropriate or ineffective, or in the interim period until radiotherapy becomes fully effective.

EFFECTIVE PRACTICE COMMITTEE RECOMMENDATION (IF AVAILABLE)

Octreotide, as a long acting depot preparation, could be used only in the treatment of acromegaly and only after the completion of a shared care prescribing guideline.

DOSAGE AND ADMINISTRATION

Initiation

Octreotide - Sandostatin LAR®: Administered by intramuscular injection once every four weeks. The usual starting dose of is 20mg every four weeks for three months.
Lanreotide - Somatuline LA®: Administered by intramuscular injection of 30mg every 14 days initially. Subsequently the frequency of injection may be increased to every 7-10 days based upon the clinical and biochemical response.
Lanreotide - Somatuline Autogel®: Administered by deep subcutaneous injection of 60mg every 28 days initially.

MAINTENANCE

The maintenance dose may be reduced if:

- GH concentrations are consistently below 1µg/L (2mU/L) after an oral glucose load test.
- IGF-1 serum concentrations have normalised.

Occasionally higher doses are used in resistant cases, which will require more frequent review in secondary care.

The site of repeat intragluteal injections should be alternated between the left and right gluteal muscle.

Individual doses will be advised by the Endocrine team based on the patient's response to treatment.

CONTRAINDICATIONS

- Hypersensitivity to lanreotide or octreotide, lactide-glycolide copolymer, lactic-glycolic copolymer, mannitol, carmellose or polysorbate 80.
- Experience with lanreotide or octreotide in pregnancy or breastfeeding is not available and thus not recommended. BNF reports possible effects on foetal growth in second and third trimesters.

PRECAUTIONS

- Impaired insulin and/or glucagon secretion is known with somatostatin analogues. In patients with concomitant diabetes mellitus; monitoring of glucose tolerance and any antidiabetic treatment is recommended.
- Patients with liver or kidney dysfunction are recommended to have organ function tested and dose adjustments made according to the results.

MONITORING – SECONDARY CARE

- Evidence of disease control should be based on normalisation of IGF-1 and reduction of growth hormone on oral glucose testing.
- IGF1 should be assessed every 6 months.
- Annual growth hormone monitoring.
- Baseline ultrasonic examination of the gallbladder and biliary system according to SPC or local protocol.
- To decide on a 6-monthly basis whether to perform ultrasonic examination of the gallbladder and biliary system during somatostatin analogue therapy (local variation on the SPC).
- Annual thyroid function tests for patients receiving therapy over 1 year in duration.
- In patients whose condition is stable annual review may be recommended.

MONITORING – PRIMARY CARE

- Increased awareness of onset or worsening of diabetes mellitus.

STOP AND REFER TO SPECIALIST TEAM IF

- Breakthrough in symptoms is seen.
- An adverse effect of the drug is noted.

ARCHIVED

Please note: Adult specialist endocrinology services are not commissioned by CCGs. NHS England commissions treatments for pituitary and hypothalamic diseases, including acromegaly. Guidance should be provided to GPs by specialist services if requests are made to share care. This shared care guideline has been archived.

SIDE EFFECTS

Very common > [1 in 10] > Common > [1 in 100] > Uncommon > [1 in 1000] > Rare > [1 in 10000] > Very rare

Very common/common

- Injection site reactions (local pain and, rarely, swelling and rash);
- GI side effects [≈ 30%] (anorexia, nausea, vomiting, cramping abdominal pain, abdominal bloating, flatulence, loose stools, diarrhoea and steatorrhoea); Steatorrhoea may respond to pancreatic enzyme treatment. Advice may be sought from the Endocrine department
- Development of gallstones has been reported in 10 to 20% of long-term recipients of s/c sandostatin though 1% of all patients appear symptomatic
- Altered glucose regulation (both hyperglycaemia [≈15%] and more rarely hypoglycaemia have been reported)

Uncommon/rare

- Symptoms resembling acute intestinal obstruction; acute pancreatitis has been reported within the first hours or days; cholelithiasis-induced pancreatitis; acute hepatitis without cholestasis (normalised on withdrawal of s/c Octreotide); slow development of hyperbilirubinaemia, transient hair loss.

COMMON/SIGNIFICANT DRUG INTERACTIONS

- May require change in antidiabetic medicine doses: (metformin, sulphonylureas, 'glitazones', 'glinides' and insulins) as somatostatin analogues can alter drug requirements due to inhibitory effects on the secretion of insulin and glucagon.
- Possible reduced intestinal absorption of ciclosporin leading to lower plasma levels
- Possible delayed absorption of cimetidine.
- Concomitant administration of somatostatin analogue and bromocriptine may increase the bioavailability of bromocriptine.
- Caution should be exercised during co-administration of octreotide and drugs mainly metabolised by CYP3A4, which have a low therapeutic index (e.g. carbamazepine, digoxin, warfarin and terfenadine).

NOTES

- Somatuline® LA and Sandostatin LAR® must be made up in the supplied solution immediately before injection, by shaking the vial, gently, 20 to 30 times, in order to obtain a homogenous suspension with a milky appearance.
- The Pituitary Foundation Web resource: **http://www.pituitary.org.uk**
  Links to support groups, patient information and general information relevant to pituitary diseases.

PRODUCT INFORMATION – prices correct at date of publication

- Sandostatin LAR® 10-mg vial = £637.50; 20-mg vial = £850.00; 30-mg vial = £1062.50 (Annual cost per patient: £8287 to £13812)
- Somatuline® LA 30mg = £310.85, Autogel: 60mg = £525, 90mg = £699, 120mg = £902 (Annual cost per patient: £6825 to £11,726)

REFERENCES:

- Summary of Product Characteristics: Sandostatin LAR® and Somatuline LA® at http://emc.medicines.org.uk/ January 2008.
- Royal College of Physicians of London, Pituitary Tumours 1997 (Recommendations for Service Provision & Guidelines for Management of Patients), 1-39. http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=178

AUTHORS:

- Dr I Lewin - Consultant Endocrinologist NDDH.
- Dr M Daly - Consultant Endocrinologist RD&E.
- Mr C Richman – Prescribing Support Pharmacist Mid Devon PCT.
- North and East Devon Health Community Shared Care Guidelines Group.
- Alice Foster – HTA Support Pharmacist Devon PCT

Date Endorsed By Effective Practice Committee: March 2008
Review Date: March 2010

ARCHIVED

Please note: Adult specialist endocrinology services are not commissioned by CCGs. NHS England commissions treatments for pituitary and hypothalamic diseases, including acromegaly. Guidance should be provided to GPs by specialist services if requests are made to share care. This shared care guideline has been archived.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of adult patients with **ACROMEGALY** who are prescribed **a SOMATOSTATIN ANALOGUE** can be shared between the specialist and the general practitioners. GPs are **invited** to participate. If the GP is not confident to undertake these roles, then 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 practical.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and be accepted by them.

The doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Specialist responsibilities:

- ❑ Initiation of drug treatment, provide the first prescription and ensure stabilisation of patient's condition.
- ❑ Provide the patient or patient's parents/guardians/carers with suitable written and verbal information about the drug prior to starting medication and discuss the benefits and side effects of treatment.
- ❑ Baseline monitoring of Insulin Growth Factor-1 and Growth hormone levels with appropriate monitoring review. Ultrasound of gallbladder at start of treatment and review at 6 month interval thereafter.
- ❑ Discuss treatment and education requirements with Endocrine nurse for communication to the patient.
- ❑ Ask the GP whether they are willing to participate in shared care.
- ❑ Provide first prescription of the drug for the patient's condition ensuring that the condition is stabilised and the GP agrees to take over responsibility for prescribing.
- ❑ Specify review dates at clinically relevant time intervals for both the GP and the consultant.
- ❑ Prompt communication with GP of any changes in treatment or dose requirements, results of monitoring undertaken and assessment of adverse events.
- ❑ Advice to GPs on when to stop treatment or alter dose.
- ❑ Provide the GP with relevant contact information with clear arrangements for back-up advice and support should further assistance be required relating to this drug.
- ❑ Reporting adverse events to the CSM.

General Practitioner responsibilities:

- ❑ Reply to request for shared care as soon as practical.
- ❑ Take on prescribing of the **somatostatin analogue** from the second prescription after communication from the specialist that the patient is stabilised.
- ❑ Prescribe 1 month of **somatostatin analogue** at a time. Keep a record of test results in the patient's notes.
- ❑ Prompt referral to a specialist if there is a change in the patient's health status.
- ❑ Reporting to and seeking advice from a specialist on any aspect of patient care which is of concern to the GP and may affect treatment.
- ❑ Reporting adverse events to the specialist and CSM.
- ❑ Stopping treatment in the case of a severe adverse event or as per shared care guideline.

Patient responsibilities:

- ❑ Report any adverse effects to their GP and/or specialist regarding their treatment.
- ❑ Ensure that they have a clear understanding of their treatment.
- ❑ Ensure they attend for monitoring requirements as per shared care guideline.
- ❑ Aware that treatment will be stopped if patient does not attend for monitoring.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No:	E-mail address
Dr M Daly	01392 402772	Mark.daly@rdeft.nhs.uk
Dr B Vaidya	01392 402772	Bijay.Vaidya@rdeft.nhs.uk
Dr A Watt	01271 322417	Alistair.watt@ndevon.swest.nhs.net
Lynn Goss (Nurse Specialist)	01392 402847	Linda.Goss@rdeft.nhs.uk

ARCHIVED

Please note: Adult specialist endocrinology services are not commissioned by CCGs. NHS England commissions treatments for pituitary and hypothalamic diseases, including acromegaly. Guidance should be provided to GPs by specialist services if requests are made to share care. This shared care guideline has been archived.

Shared Care Agreement Letter - Consultant Request

To: Dr.....

Practice Address: .....

.....

.....

Patient Name:
Hospital number:
Date of birth:
Address:

DIAGNOSED CONDITION:
.....

I recommend treatment with the following drug:
.....

I am requesting your agreement to sharing the care of this patient according to the Devon Primary Care Trust North and East Devon Health Community Shared Care Prescribing Guidelines for this drug.

Signed:	
Consultant name:	
Department:	
Contact telephone number:	
Date:	

GP RESPONSE

I agree/ do not agree* to share the care of this patient in accordance with the Shared Care Guideline.

Signed: ..... Date: .....

GP name: ..... *Delete as appropriate

ARCHIVED