NORTH AND EAST DEVON HEALTHCARE COMMUNITY SHARED CARE PRESCRIBING GUIDELINE

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

TREATMENT OF GASTROENTEROPANCREATIC TUMOURS 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 **GASTROENTEROPANCREATIC TUMOURS** prescribed **a SOMATOSTATIN ANALOGUE**. These guidelines provide additional limited information necessary to aid in the treatment of patients with **GASTROENTEROPANCREATIC TUMOURS.** 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

Gastroenteropancreatic tumours (GEPs) are rare tumours that develop in the organs of the digestive system. They usually start in the cells of the stomach, intestines and the pancreas.
GEPs include: insulinomas, gastrinomas, glucagonomas, VIPomas, somatostatinomas.
Octreotide and lanreotide are pharmacological options in relieving the symptoms of GEPs.
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.

INDICATIONS FOR THE PURPOSES OF THIS GUIDELINE

Treatment of patients with GEPs who are adequately controlled on s/c treatment with octreotide: as adjunct or alternative to surgery, radiotherapy or embolic therapy.

DOSAGE AND ADMINISTRATION

INITIATION IN SECONDARY CARE

Octreotide 50 micrograms s/c daily or twice daily increased as required to 200 micrograms three times a day. Individual cases may require higher doses. Once the patient is symptom free then a long acting product maybe considered.

MAINTENANCE

Octreotide - Sandostatin LAR®: Administered by intramuscular injection once every four weeks. The usual starting dose of is 20mg every four weeks for three months. It is recommended that the octreotide s/c is continued for 2 weeks after the first Sandostatin LAR injection.

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 into the gluteal region of 60 to 120mg every 28 days initially.

Where symptom breakthrough occurs addition of s/c octreotide and referral back to secondary care is recommended.
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

- Pregnancy and breastfeeding - 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

- Diabetes mellitus - 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.
- Liver or kidney dysfunction - Patients with liver or kidney dysfunction are recommended to have organ function tested and dose adjustments made according to the results.
- Gallstones – see over.

MONITORING – SECONDARY CARE

- Review of symptoms to ensure that the patient is appropriately treated.
- Monitoring of blood glucose at each visit.
- 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.

REFER TO THE SPECIALIST TEAM IF

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

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.

Very common/common

- Gallstone formation. 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 (normalized on withdrawal of s/c octreotide); slow development of hyperbilirubinaemia, transient hair loss.

COMMON/SIGNIFICANT DRUG INTERACTIONS

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

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 an homogenous suspension with a milky appearance.

PRODUCT INFORMATION

- 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/ on 14/5/2004.
- http://www.cancerbackup.org.uk/Cancertype/Neuroendocrine/GEPs accessed 23rd August 2006.
- BNF 55 March 2008 accessed at www.bnf.org

AUTHORS:

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- North and East Devon Health Community Shared Care Guidelines Group.
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AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

These are suggested ways in which the responsibilities for the management of adult patients with **gastroenteropancreatic tumours** 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 it is 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 as described in the Shared Care Guideline with appropriate monitoring review. Ultrasound of gallbladder at start of treatment and review at 6 month intervals thereafter.
- ❑ Ask the GP whether they are willing to participate in shared care.
- ❑ Discuss treatment and education requirements with specialist nurse for communication to the patient. If the patient or patient carer is administering then appropriate competence needs to be assessed by the specialist.
- ❑ A member of the specialist team will contact the practice to confirm arrangements are in place to safely administer the drug.
- ❑ 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 it is practical.
- ❑ Take on prescribing of the **somatostatin analogue** after communication from the specialist that the patient is stabilised.
- ❑ Prescribe 1 month of **somatostatin analogue** at a time.
- ❑ 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 Dr B Vaidya Dr A Watt Lynn Goss (Nurse Specialist) Sarah Revesz	01392 402772 01392 402772 01271 322417 01392 402847 01392 402847	Mark.daly@rdeft.nhs.uk Bijay.Vaidya@rdeft.nhs.uk Alistair.watt@ndevon.swest.nhs.net Linda.Goss@rdeft.nhs.uk Sarah.Revesz@rdeft.nhs.uk

Shared Care Agreement Letter - Consultant Request

To: Dr.....

Practice Address: .....

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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