CHUFT Guidelines for the continuing care of patients receiving long acting octreotide in the management of Gastroenteropancreatic Neuroendocrine Tumours

In Partnership with Health Authorities & GPs

This guideline aims to provide a model framework for the prescribing of long acting octreotide for the management of carcinoid syndrome by GPs, and to set out the associated responsibilities of GPs and hospital specialists who enter into shared care arrangements for patients who are treated with long acting octreotide.

Gastroenteropancreatic (GEP), neuroendocrine tumours (NETs) are rare tumours that develop in the organs of the digestive system. GEPs include insulinoma, gastrinoma, glucagonoma, VIPoma, Somatostatinoma. Although symptoms vary a number of patients present with carcinoid syndrome, especially in the presence of metastasis. Most of these tumours express a high density of somatostatin receptors that respond to the inhibitory action of octreotide and other somatostatin analogues. Inhibition of these receptors results in a decrease in the incidence and severity of commonly observed symptoms such as diarrhoea and flushing.

Treatment
Somatostatin analogues are the only proven hormonal management that inhibit somatostatin receptors hence decreasing the incidence and severity of symptoms such as diarrhoea and skin flushing. The two analogues available are octreotide and lanreotide, with octreotide being the treatment of choice.

Octreotide is available as a subcutaneous injection or a long acting depot preparation (Sandostatin LAR®). Sandostatin LAR®:

- Is available as 10mg, 20mg and 30mg powder vials supplied with diluent-filled syringes. The product must be stored between 2 to 8°C and protected from light. It can remain at room temperature on the day of injection.
- may only be administered by deep intragluteal injection. The site of repeat intragluteal injections should be alternated between the left and right gluteal muscle.
- Can be prescribed on FP10 prescriptions. The price varies depending on dose, starting from £427 for 10mg vials, £705 for 20mg and £903 for 30mg vials.

The most common adverse effects of somatostatin analogues are usually mild and resolve with time. They include reactions (pain and erythema) at injection site, abdominal cramps, nausea, flatulence, diarrhoea and steatorrhoea. There is also a risk of cholelithiasis which may be asymptomatic. Rare adverse effects include bradycardia, abnormal metabolism of glucose, malabsorption of vitamins A, B12 and D, alopecia

Treatment initiation
The following patients are suitable for initiation on treatment with octreotide:

- Patients with peptide/amine-induced syndrome with clinical symptoms
- Patients with progression of metastatic disease even without a syndrome
- Peri-operatively to avoid “carcinoid crisis”

Patients will initially be started on short acting subcutaneous octreotide by hospital specialist until symptoms are adequately controlled. The dose should be started off low, 100mcg BD – TDS or 300mcg in a syringe driver over 24 hours and increased gradually up to a maximum of 1mg daily. Once stable the patient will then be started on Sandostatin LAR® 20mg every 4 weeks by deep intramuscular injection into gluteal muscle. Patients should continue the short acting subcutaneous injection at their usual dose for two weeks after their first injection of Sandostatin LAR®. Patients will receive a further long action injection under the care of the hospital specialist and if deemed that symptoms are well controlled, further injections will be supplied and administered by the patients GP.

If symptoms are not controlled after 3 months of treatment, the dose of Sandostatin LAR® may be increased to 30mg every 4 weeks or the treating specialist may consider a decrease in administration interval from 28 days to 21 days. The decision to increase/decrease the dose, change administration interval or stop treatment remains with the hospital specialist.

Monitoring and response measurement in secondary care

- Plasma chromogranin A (CgA) and 5-hydroxyindoleacetic acid (5-HIAA) at baseline
- Baseline and 6 monthly ultrasonic examination of the gall bladder and biliary system
- Biochemical parameters every 3 to 6 months.
- Review of symptoms to ensure that patient is stable
- Monitoring blood glucose at each visit
- Annual thyroid function tests for patients receiving therapy for more than 1 year.
- Reduction in hypersecretion-related/hormonally medicated symptoms such as diarrhoea.
- More than 50% decrease in tumour markers.

Stopping treatment in Secondary care

Reasons to stop octreotide treatment include:

- Patients not tolerating octreotide injections. (If a patient, soon after commencement of treatment or later during the treatment course, develops signs of steatorrhoea (pale/oily stools, difficult to flush in the toilet), then treatment should NOT be discontinued, but the patient should be started on an oral pancreatic enzyme supplements (e.g. Creon®)
- Failure to achieve symptomatic and/or tumour growth control in spite of dose escalations
- Increase in tumour size or tumour markers (octreotide may be continued if effective in symptom control)

Monitoring in primary care

- Report any adverse events experienced by the patient to specialist in secondary care
- Refer to secondary care if there are changes in symptoms

Specialist Responsibilities

- Initiation of drug treatment, provide first prescription and ensure stabilisation of patient's condition.
- Provide the patient or 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 shared care guideline with appropriate monitoring review.
- Provide the GP with a full summary letter giving the patient's clinical and treatment details before implementation of shared care is requested
- Complete GP request to participate in shared care
- If patient/carer is administering the drug, ensure competency.
- Provide first two prescription of long acting preparation
- Advice to GPs on when to stop or alter treatment

General practitioner responsibilities

- Reply to request for shared care as soon as practical.
- Take on prescribing of Sandostatin LAR® after communication from the specialist that the patient is stabilised.
- Prescribe 1 month of Sandostatin LAR® at a time.
- Prompt referral to a specialist if there is a change in patient's symptoms
- 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.

GPs are encouraged to accept the prescribing of long acting octreotide in line with this shared care protocol. If, however the GP is unwilling to accept prescribing responsibility for long acting octreotide, the consultant should be informed as soon as possible to ensure that the continuity of the patients treatment is not jeopardised. If the GP, supported by the CCG Medicines Management Team, refuses to prescribe a drug for clinical or professional reasons, then prescribing responsibility should remain with the consultant. Refusal to prescribe should not be based on grounds of cost.

Consultant and Senior Hospital Staff support

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Oncology Pharmacist	Debbie Whittle/ Oncology Pharmacy Team	01206 746221
Pharmacy Medicines Information		01206 742161

Reference: ECN Long acting octreotide in the management of symptoms associated with gastroenterhepaticpancreatic tumours and neuroendocrine tumours – continuing care guidelines.

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AUTHOR: Debbie Whittle

Shared Care Agreement Letter

Colchester Hospital University NHS
NHS Foundation Trust

GP Name & address

Consultant Name & address

Date

Long acting Octreotide (Sandostatin LAR®) injection

……..mg

Patient Name:

Patient Hospital number:

Patient Address:

Patient NHS Number:

Dear Dr,

Your patient has been initiated on Sandostatin LAR® ….mg for the management of symptoms associated with associated with gastroenteropancreatic neuroendocrine tumours.

I am requesting your agreement to sharing the care of this patient according to the CHUFT Shared Care guideline. Please sign both copies of this letter to indicate your agreement and return one copy to my office; the other should be placed in the patient's notes at your practice.

Yours sincerely,

<Insert consultant name

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 _____