

# Lanreotide (Somatuline Autogel®) (TLS amber)

## Shared Care Guideline: Acromegaly

### AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of lanreotide (Somatuline Autogel®) in patients with Acromegaly are shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is 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 practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Acromegaly are under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

**The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

### RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Initiate treatment and stabilise on lanreotide this usually involves prescribing at least the first 3 months of treatment.
2	Discuss the benefits and side effects of treatment with the patient.
3	Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient.
4	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
5	Review the patient's condition and monitor response to treatment regularly where indicated.
6	Advise the GP on the dose to prescribe, when to adjust the dose, stop treatment, or consult with the specialist
7	If diabetic patient advise the GP of potential effects on insulin secretion.
8	Report adverse events to the MHRA and GP
9	Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities	
1	Reply to the request for shared care as soon as practicable.
2	Prescribe lanreotide (Somatuline Autogel®) at the dose recommended.
3	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms) or intolerance to therapy occurs.
4	Carry out the required monitoring and discuss any abnormal results with the specialist.
5	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
6	Stop treatment on the advice of the specialist.
7	Report adverse events to the MHRA.

Patient's role	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Share any concerns in relation to treatment with medicine.
3	Report any adverse effects to the specialist or GP whilst taking the medicine.

### BACK-UP ADVICE AND SUPPORT (To be completed by RUH staff)

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Hospital Pharmacy Dept:				
Other:				

## **MONITORING**

### **Secondary care**

The hospital specialist will perform ongoing medical and biochemical assessment of response to therapy, including pituitary function tests, pituitary imaging and visual field measurement, where relevant; and consider additional or alternative therapies where necessary.

Yearly specialist follow up will be the usual requirement

### **Primary care**

When treatment is established, efficacy monitoring is by 6-monthly blood IGF-1 measurements, ideally achieving levels in the mid-upper part of the normal range.

Normal IGF-1 levels depend on age and gender, and the reference numbers may vary slightly depending on which laboratory provides the results.

If there is any loss of control of blood sugar in diabetic patients the GP can adjust anti-diabetic treatment as necessary.

However the GP could liaise with the specialist if there is:

- Loss of control of symptoms of acromegaly
- Symptoms of gallstones
- Unacceptable increases in side effects(eg gastrointestinal, injection site reactions)
- Pregnancy
- Need for advice at any time they consider necessary.

## **SUPPORTING INFORMATION**

### **Licensed indications**

Lanreotide (Somatuline autogel®) is licensed for the treatment of individuals with acromegaly when the circulating levels of growth hormone (GH) and /or insulin-like growth factor-1(IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels and where possible to normalise these values.

Acromegaly is a rare growth disorder 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.

Clinical features of the disease include: course facial features, enlargement of the hands and feet, soft tissue thickening (carpal tunnel syndrome) , headache, excessive sweating, prognathism, separation of teeth and macroglossia, obstructive sleep apnoea, cardiovascular disease ( hypertension, cardiomyopathy) arthralgia (accelerated osteoarthritis), impaired glucose tolerance/diabetes mellitus and goitre.

It is a disabling and disfiguring disease that is associated with 2 to 3 fold increase in mortality, with an increased risk of death from cardiovascular disease, respiratory disease and colon cancer. All cause mortality, cancer and cardiovascular death rates are reduced to that of the reference population when GH levels are normalised.

### **Indications for the purpose of this guideline**

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

### **Treatment goals**

The main goals of treatment are to reduce tumour volume, ameliorate symptoms, reduce GH hypersecretion and maintain normal levels of other pituitary hormones.

### **Treatment Schedule (including dosage and administration)**

The recommended dose is 60 – 120mg administered every 28 days.

The GP will be advised of the dose the patient has been stabilised on by the hospital consultant.

- The dose will require to be administered by a nurse.
- The dose is given by deep subcutaneous injection into the superior external quadrant of the buttock.
- The needle should be inserted rapidly to its full length, perpendicularly to the skin.
- No dose adjustments are needed for renal or liver impairment or in elderly patients.
- Treatment should be continued for as long as the patient is responding –getting relief of symptoms
- Lanreotide must be stored in a fridge.

### **Contraindications and precautions for use**

Lanreotide is contraindicated in:

- Hypersensitivity to lanreotide or related peptides

### **Precautions**

- Diabetic patients may experience changes in blood glucose levels. Monitor.
- Slight decreases in thyroid function may occur.

### **Side Effects**

The most commonly reported adverse effects associated with lanreotide are gastrointestinal effects including diarrhoea, abdominal pain, nausea, constipation and flatulence.

Gall stones are also a common side effect.

Less common side effects include pain at the site of the injection, hot flushes, leg pain, and abnormal glucose tolerance.

Refer to the SPC for a full list of adverse effects.

*Lanreotide (Somatuline autogel) no longer has black triangle (⚠) status.*

*Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the CHM.*

### **Drug Interactions**

The gastrointestinal effects of lanreotide may reduce the intestinal absorption of co-administered drugs.

Blood levels of cyclosporin are reduced by lanreotide

### **Cost**

At current prices one year's treatment with lanreotide 120mg monthly costs £10,840

NB At current prices one year's treatment with octreotide 30mg monthly costs £12,744

### **References**

IPSEN Somatuline Autogel *Summary of Product Characteristics* 2003.

BNF 58 September 2009

### **Date of review**

To be reviewed January 2012

### **Document details**

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