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SHARED CARE GUIDELINE: OCTREOTIDE for the treatment of acromegaly

General Principles

Shared Care Responsibilities:
In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF* 59, March 2010, pg.4)

Aims:
(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.

(2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.

(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.

(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between the Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies

Further copies of any guidelines in this series are available from NHS Lincolnshire Prescribing Advisers.

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Drug Details

Approved Name: Octreotide
Brand Name: Sandostatin Lar
Form and Strength: Depot injections 10mg, 20mg and 30mg

Specialist Responsibilities

The specialist secondary/tertiary care service will:

- Send a letter to the GP suggesting that shared care is agreed for this patient.
- Ensure that the patient receives supplies of octreotide from the hospital or prescribed on FP10HP until the GP formally agrees to share care.
- Carry out baseline monitoring of Insulin Growth Factor-1 and Growth hormone levels, communicating the results to the GP.
- Be responsible for all routine monitoring whilst patient remains on this treatment. This includes monitoring of Insulin Growth Factor - 1 and Growth hormone levels and thyroid function.
- Arrange an ultrasound examination of the gallbladder at start of treatment and review at 6 month interval thereafter.
- Initiate treatment with octreotide and ensure stabilisation of patient's condition before care is transferred to the GP. Once controlled on octreotide subcutaneous injections patients may be transferred to the long acting depot (LAR) that requires once a month administration.
- Be responsible for transferring the patient on to the long acting depot preparation and provide the GP with clear instructions as to what the dose is.
- Provide the patient with suitable written and verbal information about the drug prior to starting medication and discuss the benefits and side effects of treatment.
- Specify review dates at clinically relevant time intervals for both the GP and the consultant.
- Communicate promptly any changes in treatment or dose requirements, results of monitoring undertaken and assessment of adverse events, to the GP.
- Notify the GP if patient fails to attend for appropriate monitoring and advise GP on appropriate action.
- Advise the GPs on when to stop treatment.
- 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.
- Report adverse events to the CSM.

GP Responsibilities

The GP will:

- Notify the consultant in writing, within two weeks, if they agree to share care.
- Take on prescribing of the Octreotide from the second prescription after communication from the specialist that the patient is stabilised.
- Make the necessary arrangements for the regular intramuscular administration of octreotide including that of the initial dose if requested by consultant.
- Carry out monitoring as requested by specialist keeping a record of test results in the patient's notes.
- Promptly refer to a specialist if there is a change in the patient's health status.
- Report and seek advice from a specialist on any aspect of patient care which is of concern to the GP and may affect treatment.
- Report adverse events to the specialist and CSM.
- Stop treatment in the case of a severe adverse event or as per shared care guideline and

Referral Criteria

The specialist will have carried out an assessment of efficacy.
Patients will have received at least 1 month of octreotide therapy on hospital prescription.

Licensed Indications

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.

Recommended Dosage and Administration

Initiation:
Treatment with octreotide is usually initiated using the 50 micrograms per ml subcutaneous injection. Initial dose 100-200 micrograms three times daily. Treatment should be discontinued if no clinical improvement within 3 months.

Octreotide - Sandostatin LAR®: - administered by intramuscular injection once every four weeks. The usual starting dose of is 20mg every four weeks for three months. The dose is then adjusted according to symptom control and laboratory test results. The maximum dose is 30mg every four weeks.
Depot octreotide is started one day after the last dose of subcutaneous octreotide.
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.

Background Pharmacology

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.
Octreotide is an analogue of the hypothalamic release-inhibiting hormone somatostatin. 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.

Preparations Available

Octreotide depot injection (Sandostatin Lar) - 10mg, 20mg and 30mg

Adverse Effects

Main effects are local and gastrointestinal:

1. Pain, swelling and rash at injection site – this reaction rarely persists longer than 15 minutes and can be reduced by allowing the octreotide solution to reach room temperature before administration.
2. Anorexia
3. Nausea and vomiting
4. Abdominal pain
5. Abdominal bloating and flatulence
6. Loose stools, diarrhoea and steatorrhoea
7. Gallstones, associated with long term administration
8. Impaired glucose tolerance due to inhibition of insulin secretion – may reduce requirements for insulin, metformin, repaglinide and sulphonylureas
9. May increase depth and duration of hypoglycaemia if patient also has insulinoma

For a complete list of possible side effect please refer to the latest version of the SPC

Drug Interactions

- Reduced absorption of ciclosporin
- Delayed absorption of cimetidine
- Increased 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).

Contraindications

Known hypersensitivity to octreotide or any component of the formulation

Precautions

15 – 30% of patients develop gallstones – ultrasonic examination of the gallbladder is recommended before and at intervals of 6-12 months during treatment
Thyroid function should be monitored annually in patients on long term treatment
Diabetic patients should be monitored for the need for changes to anti diabetic therapy

Pregnancy and Breast Feeding:

Experience in pregnancy is limited –should not be used except solely under care of the specialist
Use in breastfeeding is contra-indicated

Monitoring - (Secondary care)

Evidence of disease control should be based on normalisation of IGF-1 and reduction of growth hormone on oral glucose testing.

All routine monitoring is the responsibility of the specialist service.

- GF1 should be assessed every 6 months.
- Annual growth hormone monitoring.
- Baseline ultrasonic examination of the gallbladder and biliary system
- To decide on a 6-monthly basis whether to perform ultrasonic examination of the gallbladder and biliary system during Somatostatin analogue therapy
- Annual thyroid function tests for patients receiving therapy over 1 year in duration.
- In patients whose condition is stable annual review may be recommended.

Indication of Likely Cost of Therapy in Primary Care

Octreotide 20mg depot injection	- £850.00
Octreotide 30mg depot injection	- £1062.50

Information given to the Patient

Patient information leaflet

Contact Details

Dr K Sands Consultant Diabetologist Lincoln Hospital ext 2925

References;

BNF 59 March 2010.
MIMS August 2010
Sandostatin Lar - Summary of Product Characteristics, April 2010
Sandostatin Lar - Patient Information leaflet, April 2010.
Bro Taf Localities Drugs and Therapeutics Committee Shared Care- Octreotide protocol number CV 33.

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