Lincolnshire Primary Care Trust

LINCOLNSHIRE PRIMARY CARE TRUST in association with UNITED LINCOLNSHIRE HOSPITAL TRUST

Draft

SHARED CARE GUIDELINE: OCTREOTIDE for the symptomatic relief of malignant intestinal obstruction, secretory fistulae and profuse diarrhoea

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*, 51, March 2006, p. 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 County-Wide PCT Prescribing Group 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 PCT Prescribing Advisers.

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Drug Details

Approved Name: Octreotide
Brand Name: Sandostatin and Sandostatin Lar
Form and Strength: Ampoules 50mcg/ml, 100mcg/ml and 500mcg/ml
Multidose vials 1mg/5ml
Depot injections 10mg, 20mg and 30mg

Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Send a letter to the GP suggesting that shared care should be considered for this patient.
2. Ensure that the patient receives supplies of octreotide from the hospital or prescribed from the hospital on FP10HP until the GP formally agrees to share care.
3. Carry out baseline tests prior to commencing therapy – see monitoring section
4. Specify a dosage regime together with a schedule of dose changes and communicate these to primary care team.
5. Assess any likely modifications to diabetic medication and advise the patient and the GP of the action taken.
6. Periodically review the patient's clinical condition.
7. Provide back up and support facilities e.g. advise on dosage alterations where appropriate.
8. Evaluate any adverse events reported by GP

GP Responsibilities

The GP will:

1. Notify the consultant in writing, without undue delay, if they agree to share care.
2. Prescribe the octreotide in accordance with the dosage schedule.
3. Monitor the patients overall health and wellbeing.
4. Monitor the patient for adverse drug reactions and remain vigilant to the risk of potential drug interaction.
5. Monitor diabetic treatment if appropriate.
6. Report any suspected adverse drug reactions to the specialist centre.

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

This indication is **unlicensed** but the BNF (edition 52 Sept 2006 p17) states "octreotide which stimulates water and electrolyte absorption and inhibits water secretion in the small bowel, can be used by subcutaneous infusion at a dose of 300 – 600microgram / 24 hours to reduce intestinal secretions and vomiting"

Recommended Dosage and Administration

The subcutaneous preparation should be used initially until adequate control is achieved. The dose range varies according to indication and clinical response. The usual range is between 300 – 600 micrograms daily.
Once control is achieved the patient may be switched to the depot formulation. The initial dose is 20mg by deep intragluteal injection every 4 weeks, for 3 months then re-assess - maximum depot dose is 30mg every 4 weeks.
N.B the previously effective subcutaneous dose should be maintained for 2 weeks after the first depot injection.

Background Pharmacology

Octreotide is an analogue of the hypothalamic release-inhibiting hormone somatostatin. It is effective in reducing peptide hormone secretion from gastroenteropancreatic and carcinoid tumors (licensed indication)
In this particular situation (unlicensed use), octreotide provides symptomatic relief by decreasing gastrointestinal secretion of water, sodium and chloride and increasing electrolyte absorption. This reduces intestinal luminal content and breaks the cycle or secretion and distension. Octreotide may also inhibit peristalsis and encourage bowel relaxation.

Preparations Available

Octreotide Injections (Sandostatin)	-	50microgram / ml 100 microgram / ml 200 microgram / ml 500 microgram / ml
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

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

Baseline:

Physical examination
U/Es, blood sugars
Renal function, LFTs
Thyroid function test
Ultrasound examination of gall bladder and biliary system

During therapy:

Assessment of symptom control – every 3 months
Thyroid function test – annually
Ultrasound examination of gall bladder and biliary system – annually

Indication of Likely Cost of Therapy in Primary Care

Octreotide 200 microgram / ml (5ml vial)	- £65.10
Octreotide 20mg depot injection	- £850.00
Octreotide 30mg depot injection	- £1062.50

Information given to the Patient
Patient information leaflet

Contact Details

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References;

BNF 51 March 2006. BNF.org

Sandostatin summary of product characteristics, Dec 2004.
Sandostatin Lar summary of product characteristics, June 2004
Sandostatin patient information leaflet, April 2003.

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