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Cinacalcet

Endocrinology / Renal Shared Care Guideline

Specialist Details	Patient Identifier
Name: _____	
Location: _____	
Tel: _____	**Date:** _____

Introduction

Hyperparathyroidism (HPT) is an increase in parathyroid hormone (PTH) - which controls concentrations of calcium and phosphate in the blood. Cinacalcet is a calcimimetic agent which directly lowers PTH levels by increasing the sensitivity of the calcium sensing receptor to extracellular calcium. The goals of treatment are to lower levels of PTH, maintain serum calcium and phosphate levels, in order to prevent progressive bone resorption and the systemic consequences of deranged serum calcium and phosphate.

Licensed indications:

- Treatment of secondary HPT in patients with end stage renal disease on dialysis therapy
- Reduction of hypercalcaemia in patients with either parathyroid carcinoma, or primary HPT in whom parathyroidectomy is not possible or appropriate.

Adult dosage and administration

Dose adjustments if necessary are made every 2 - 4 weeks. Cinacalcet should be taken with food or shortly after a meal.

Secondary HPT in patients with end stage renal disease on dialysis therapy

The recommended starting dose is 30 mg orally once daily. Although this may be titrated to a maximum of 180 mg once daily, the usual maintenance dose is 30 mg once daily. Some renal units may recommend a starting and/or maintenance dose of 30 mg three times weekly.

Primary HPT and Parathyroid Carcinoma

The recommended starting dose is 30 mg twice a day. This can be titrated to a maximum of 90 mg four times a day according to response.

Available as: Cinacalcet 30 mg, 60 mg and 90 mg tablets.

Monitoring

Baseline tests are carried out in secondary care as part of the initial diagnosis and management. Responsibility for ongoing PTH and serum calcium monitoring is as below. Patients with renal disease are monitored by secondary care.

Test	Renal (all monitoring by secondary care)	Endocrinology (PTH monitored by secondary care, calcium monitored by primary care)
PTH	Every 1 - 4 weeks after initiation or dosage adjustment. Then every 1 - 3 months.	When required at the specialist's discretion.
Serum Calcium	Within 1 week of initiation or dosage adjustment. Then every month, or more frequently at the discretion of the specialist.	Within 1 week of initiation or dosage adjustment. Then every 2 - 3 months.

Hospital specialist responsibilities

- Diagnose the condition and assess if the patient is suitable for treatment with cinacalcet
- Arrange shared care with the patient's GP
- Provide patient/carer with relevant (preferably written) information on use, side-effects and need for monitoring of medication
- Undertake the baseline tests and communicate to the GP that these have been done
- Provide the GP with relevant information for each patient including treatment to be undertaken by GP (dose, any dose adjustments etc.) and system of monitoring
- Review results of safety monitoring and request additional tests as required
- Monitor response to treatment and need to continue therapy. The specialist will advise the GP on any dose adjustment required
- Continue to review the patient at agreed specified intervals (or when requested by the patient's GP), sending a written summary to the GP whenever the patient is reviewed
- Provide other advice or information on cinacalcet for the GP if required
- Advise the patient to inform the specialist of any change in their smoking status.

GP responsibilities

- Prescribe cinacalcet according to dose advised by specialist; continued prescribing is appropriate for patients attending regular review
- Monitor serum calcium (endocrinology patients only), ensuring practice systems are in place to recall patients for blood tests
- Adjust the dose as advised by the specialist
- Report to / seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment
- Stop treatment in presence of symptomatic hypocalcaemia, or other adverse event
- Report adverse drug reactions to initiating specialist and usual bodies (e.g. CHM, MHRA)
- Ensure no significant drug interactions with other medicines.

Adverse effects, precautions and contraindications

Contraindications: Cinacalcet should not be initiated in patients with serum calcium (corrected for albumin) below the lower limit of the normal range.

Caution advised with: moderate to severe hepatic impairment; there is potential for 2-4 fold higher plasma levels of cinacalcet in these patients; in patients with conditions that may worsen with a decrease in serum-calcium concentrations, including predisposition to QT-interval prolongation, history of seizures, and history of impaired cardiac function

Commonly reported side effects: Appetite decreased; asthenia; back pain; constipation; cough; diarrhoea; dizziness; dyspnoea; electrolyte imbalance; gastrointestinal discomfort; headache; hypersensitivity; hypotension; muscle complaints; nausea; paraesthesia; rash; seizure; upper respiratory tract infection; vomiting.

Less common side effects include: Heart failure aggravated; QT interval prolongation; ventricular arrhythmia.

Pregnancy: There are no clinical data from the use of cinacalcet during pregnancy. Use should only be considered if the potential benefit justifies the potential risk to the foetus.

Breast feeding: Cinacalcet is contraindicated in breastfeeding mothers.

Common drug interactions

Use cinacalcet with caution in association with:

- Strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or strong inducers (e.g. rifampacin). Dose adjustment of cinacalcet may be required if a patient receiving cinacalcet initiates or discontinues these.
- Medicines predominantly metabolised by CYP2D6 (e.g. flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine). Cinacalcet may increase the exposure to these medicines.
- Concurrent use of other medicines known to reduce serum calcium may result in an increased risk of hypocalcaemia, etelcalcetide should not be given concurrently
- Dose adjustment may also be necessary if a patient starts or stops smoking.

Communication

For any queries relating to this patient's treatment with cinacalcet, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects.
Please refer to full prescribing data in the SPC or the BNF

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