Western Locality Shared care information for the prescribing of cinacalcet

April 2013

Specialist: Please complete the Shared Care letter sending a request to GP (see bottom of the page)

GP: Please indicate whether you wish to share patient's care by completing letter and return to specialist

Aim of treatment

Cinacalcet is used to treat secondary hyperparathyroidism (SHPT) in patients with end stage renal disease on dialysis therapy.

- Secondary HPT is associated with increases in parathyroid hormone (PTH) - the hormone which controls concentrations of calcium and phosphate in the blood.
- The goals of treatment are to lower levels of PTH, maintain normal calcium and phosphorous levels, prevent progressive bone resorption and the systemic consequences of elevated serum calcium and phosphate.
- Cinacalcet directly lowers PTH levels by increasing the sensitivity of the calcium receptors to extracellular calcium.

Cinacalcet is recommended by NICE (TA 117 Jan 2007) for the treatment of refractory hyperparathyroidism in patients with end-stage renal disease (including those with calciphylaxis) only in those:

- who have very uncontrolled plasma levels of intact parathyroid hormone (defined as greater than 85 pmol/l (800pg/ml) that are refractory to standard therapy, and a normal or high adjusted serum calcium level, **and**
- in whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits.

Response to treatment should be monitored regularly and treatment should be continued only if a reduction in the plasma levels of intact parathyroid hormone of 30% or more is seen within 4 months of treatment, including dose escalation as appropriate.

Clinical studies have consistently demonstrated that elevated PTH, calcium and phosphate due to SHPT are associated with increased morbidity and mortality, with clinical manifestations of SHPT such as soft tissue and vascular calcification, and cardiovascular complications including death. Cinacalcet has also been shown to reduce the incidence of fractures and the need for parathyroidectomy.

Specialist responsibilities

1. Diagnose the condition and assess if the patient is suitable for treatment with cinacalcet.
2. To initiate treatment. Patients will have received at least 4 months of treatment, and have been stabilised on a suitable dose
3. Confirm shared care by letter with the patient's GP - include the shared care guideline.
4. Provide the GP with relevant information for each patient, including:
    a. Treatment to be undertaken by GP (dose, any dosage titrations etc)
    b. System of monitoring
5. Discuss with the patient relevant information on use, side effects and need for monitoring of medication.
6. Monitor response to treatment. **All monitoring will be undertaken at the renal unit. The specialist will advise the GP on any dosage adjustment required.**

7. Agree to review patient's condition when requested by the patient's GP.
8. Review the treatment regularly sending a written summary to the GP if any change in Cinacalcet therapy occurs.
9. Provide other advice or information on Cinacalcet therapy which the GP feels is required.
10. Advise the patient to inform the renal unit / nephrologist of any change in their smoking status.

General practitioner responsibilities

If GP has agreed to share care:

1. Reply to the request for shared care as soon as practicable.
2. Prescribe cinacalcet at the dose recommended.
3. Adjust the dose as advised by the specialist.
4. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
5. Stop treatment in presence of symptomatic hypocalcaemia, or other adverse event
6. Ensure no drug interactions with other medicines.
7. Report adverse events to the specialist

Back-up advice and support

Renal

- Dr P Rowe 01752 792463
- Dr R McGonigle 01752 792462
- Dr W Tse 01752 517580
- Dr I Saif 01752 792467
- Dr H Cramp 01752 245119

Derriford Medicines Information: 01752 439976

Medicines Optimisation Teams

- NEW Devon CCG, Western Locality 01752 398800
- Kernow CCG 01726 627953

Supporting Information

Preparations

Cinacalcet is available as 30mg, 60mg and 90mg tablets.

Dose

The recommended starting dose is 30mg orally once daily. Although this may be titrated to a maximum of 180mg once daily, the usual maintenance dose is 30mg once daily. Cinacalcet should be taken with food or shortly after a meal.

Contraindications

- Hypersensitivity to the active substance or any of the excipients.
- Safety and efficacy have not been established in patients below the age of 18 years.
- Pregnancy and breastfeeding: 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. Cinacalcet is contraindicated in breastfeeding mothers.

Cautions

- Cinacalcet treatment should not be initiated in patients with a serum calcium (corrected for albumin) below the lower limit of the normal range. Since cinacalcet lowers serum calcium, patients should be monitored carefully for the occurrence of hypocalcaemia.
- Adynamic bone disease may develop if PTH levels are chronically suppressed below approximately 1.5 times the upper limit of normal with the iPTH assay. If PTH levels decrease below the recommended target range in patients treated with Cinacalcet, the dose of Cinacalcet and/or vitamin D sterols should be reduced or therapy discontinued.
- The threshold for seizures is lowered by significant reductions in serum calcium levels.
- Use in hepatic impairment: use cautiously in patients with moderate to severe hepatic impairment; there is potential for 2-4 fold higher plasma levels of cinacalcet in these patients.

Side effects

(Refer to SPCs for further information)

Relatively common adverse effects include:

- Nausea, vomiting, dizziness, paraesthesia, reduced testosterone concentrations, rash, myalgia, asthenia.

Hypocalcaemia. A reduction in serum calcium is part of the pharmacological effect of cinacalcet, however, symptomatic hypocalcaemia may occur.

Less common side effects are: seizure, dyspepsia.

Interactions

(Refer to the BNF for further information)

Dose adjustment of cinacalcet may be required if a patient receiving cinacalcet initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or strong inducer (e.g. rifampicin).

Dose adjustment may also be necessary if a patient starts or stops smoking.

Shared Care Agreement Letter – Consultant Request

To: Dr.....

Practice Address.....

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Patient Name:	
NHS Number:	
Date of birth:	
Address:	

Diagnosed condition: .....

I recommend treatment with the following drug: .....

At the following dosage: .....

I request your agreement to sharing the care of this patient according to the Western Locality Shared Care Information guidelines for this drug. The patient has been initiated on treatment and stabilised in accordance with the appropriate Shared Care Information.

Principles of shared care:

GPs are invited to participate, but **if the GP is not confident to undertake these roles then they are under no obligation to do so.** If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them.

Remember: the doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Signed:			Date:
Consultant name:			
Telephone number:		Fax number	
Email address			

Please sign below and return promptly. Remember to keep a copy of this letter for the patient's records. If this letter is not returned shared care for this patient will not commence.

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: …….. *Delete as appropriate.