City and Hackney Clinical Commissioning Group
Homerton University Hospital Foundation Trust

Cinacalcet
For Uncomplicated Primary Hyperparathyroidism in Adults

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AS AND FILED IN NOTES

Patient Name:	**Date of Birth:**	**NHS No:**
Name of Referring Consultant:		**Contact number:**

INTRODUCTION – Indication and Licensing

While potent bisphosphonates have been shown to be effective in lowering serum calcium in primary hyperparathyroidism, cinacalcet is the only drug treatment currently available, which is effective for both, lowering serum calcium and serum PTH.

In patients with mild hypercalcaemia treatment with cinacalcet has shown to normalise serum calcium levels for up to three years. In patients with severe hypercalcaemia cinacalcet lowered serum calcium ≥0.25mmol/L, which represents a clinically significant reduction. However, normalisation of calcium levels could not be achieved in these patients. The calcium lowering effect of cinacalcet appears to sustain over a prolonged period of time as shown in patients with mild hypercalcaemia due to primary hyperparathyroidism-3years (Shoback et al, 2003). In patients with severe hypercalcaemia due to primary hyperparathyroidism, cinacalcet was effective when used for a mean of 16 weeks (Silverberg, 2004).

In the UK cinacalcet is licensed for use in secondary hyperparathyroidism, hypercalcaemia of primary hyperparathyroidism and parathyroid carcinoma. In endocrinology, cinacalcet will be used for the treatment of primary hyperparathyroidism after at least one failed attempt at parathyroidectomy or in those patients with primary hyperparathyroidism in whom surgery is contraindicated and fulfil one or more of the following criteria:

- Overt manifestation of primary hyperparathyroidism (e.g. nephrolithiasis, osteitis fibrosa cystica, neuromuscular disease)
- Corrected serum calcium ≥3mmol/L
- PTH≥6.5pmol/L
- Urine Calcium>10mmol/24hours
- Bone density reduced at any site to a T score of <2.5mmol/L (osteoporosis)
- Impaired renal function
- Creatinine clearance reduced by ≥30%
- Young Age (Age<50years)

PATIENT PATHWAY

Clinical Speciality / Indication	Prescribing Initiated by	Prescribing Continued by (detail when suitable for transfer to occur)	Monitored by (detail when suitable for transfer to occur IF APPROPRIATE)	Duration of treatment
Endocrinology	Endocrine team at The Homerton University Hospital	GP – once stabilised, with a minimum duration of 3 months	Endocrine Team	Long term

The endocrine team at the Homerton University Hospital would initiate and titrate the dose of this medicine. Once the dose is stable, the GP would be asked to take over prescribing as part of shared care.

For some patients, it maybe more appropriate for phlebotomy to be undertaken locally and administration to be carried out near to the patient's address by the GP if agreed by all parties. In this case, blood results should be sent to the endocrine department at the Homerton University Hospital for monitoring by the team.

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ORAL DOSE AND ADMINISTRATION

For treatment of uncomplicated primary hyperparathyroidism, cinacalcet will be initiated by the hospital at 30mg twice daily. The dose of Cinacalcet may be titrated often at 2 to 4 weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily, and 90 mg three or four times daily as necessary to normalise serum calcium levels.

Cinacalcet to be taken orally with food or shortly after a meal as the bioavailability is increased when taken with food. Tablets should be swallowed whole and not divided.

It is important not to change doses without consultation with the endocrinologists in the hospital.

MONITORING STANDARDS FOR MEDICATION AT THE ACUTE NHS TRUST

All monitoring is to be carried out by the hospital team unless otherwise agreed.

Avoid in patients who may be hypersensitive to the active substance or to any of the excipients.

Parameter	Frequency Of Monitoring	Action
Serum calcium	Monitor levels within 1 week after initiation or dose adjustment	Once maintenance dose levels have been established, monitor serum calcium every 2 to 3 months. Consider discontinuation if relevant reductions in serum calcium are not maintained. Threshold for seizures is lowered by significant reductions in serum calcium levels.
Hepatic impairment	Monitor closely during dose titration and continued treatment.	Use cinacalcet with caution in patients with moderate to severe hepatic impairment. Avoid concomitant administration with strong inhibitors or inducers of CYP3A4 and/or CYP1A2 as there is an approximate 2-fold increase in cinacalcet levels.
Lactose intolerance		Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

KEY ADVERSE EFFECTS & ACTIONS

This section should be read in conjunction with the manufacturer's data sheet.

Adverse effects	Symptoms/signs	Actions
GI disturbances	Nausea, vomiting	Take with or shortly after a meal
Metabolism and nutrition disorders	Anorexia	Refer to Endocrinologist
Nervous system disorders	Dizziness, convulsions, paraesthesia	Refer to Endocrinologist
Skin and subcutaneous tissue disorders	Rash	Refer to Endocrinologist
Musculoskeletal, connective tissue and bone disorders	Myalgia, cramping, tetany	Refer to Endocrinologist
General disorders and administration site conditions	Asthenia-general muscle weakness	Refer to Endocrinologist
Biochemical investigations	Hypocalcaemia and reduced testosterone levels	Refer to Endocrinologist
Post-marketing safety surveillance:	Allergic reactions, including angioedema and urticaria	Refer to Endocrinologist

This only lists the key important adverse reactions– For comprehensive information on cautions, contra-indications and interactions please refer to the current British National Formulary and Summary of Product Characteristics.

PREGNANCY AND BREAST FEEDING

Pregnancy: No clinical data from the use of cinacalcet in pregnant women. Animal studies do not indicate direct harmful effects with respect to pregnancy, parturition or postnatal development.). Cinacalcet should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Breast-feeding: It is unknown whether cinacalcet is excreted in human milk. Following careful benefit/risk assessment, a decision should be made to discontinue either breast-feeding or treatment with cinacalcet.

Fertility: There are no clinical data relating to the effect of cinacalcet on fertility. There were no effects on fertility in animal studies.

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics.

SHARED CARE

Shared care guideline*:* is a document which provides information allowing patients to be managed safely by primary care, secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and also sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. Intrinsic in the shared care agreement is that the prescribing doctor should be appropriately supported by a system of communication and cooperation in the management of patients. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use**.**

Consultant

1. Ensure that the patient/carer is an informed recipient in therapy.
2. Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.
3. Ensure baseline investigations are normal before commencing treatment. Give the patient a patient held booklet for result monitoring if appropriate.
4. Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first month of treatment or until patient is stabilised).
5. Send a letter to the GP requesting shared care for this patient.
6. Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
7. Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter e.g. from Endocrinologist or Pharmacy Drug Monitoring Service).
8. Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP
9. Evaluation of any reported adverse effects by GP or patient.
10. Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
11. Inform GP of patients who do not attend clinic appointments.
12. Counsel the patient on contraception and what to do if pregnancy occurs. Document in the notes.
13. Ensure that backup advice is available at all times.
14. Ensure, where timing is appropriate, that the patient has received a flu vaccine prior to commencing treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given

SHARED CARE - continued

General Practitioner

1. Ensure that the patient understands the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Monitor patient's overall health and well-being.
3. Report any adverse events to the consultant, where appropriate.
4. Report any adverse events to www.mhra.gov.uk/yellowcard where appropriate.
5. Help in monitoring the progression of disease
6. Prescribe the drug treatment as described.

City and Hackney Medicines Management Team

1. To provide feedback to acute trusts via Joint Prescribing and Medicines Management Group
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support acute trusts in resolving issues that may arise as a result of shared care.

Patient/ Carer

1. Report any adverse effects to their GP and/or specialist
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
5. Take/ administer the medication as prescribed
6. Undertake any monitoring as requested by the GP and/or specialist

Costs

Drug: Cinacalcet (Mimpara®) 30mg x 28 tablets = £125.75 60mg x 28 tablets = £231.97 90mg x 28 tablets = £347.96	Cost of one month's therapy from MIMS (DECEMBER 2013) • 30mg BD = £ 252 • 60mg BD = £464 • 90mg BD = £696 • 90mg QDS = £1392

Relevant contact details

Consultant via switchboard	020 8510 5555
Registrar on-call out of hours	020 8510 5555
Lloyd Ward (Endocrine)	020 8510 7530 020 8510 7531
Medicines Information Pharmacist Homerton University Hospital	020 8510 7000
City and Hackney Medicines Management Team	020 3688 1037

Reference

- Summary of Product Characteristics – Cinacalcet AMGEN; Last updated 19.09.2013; http://www.medicines.org.uk/EMC/medicine/15432/SPC/Mimpara/ [Accessed 16/12/2013]
- SCG adopted from NHS Tower Hamlets CCG and Barts Health NHS Trust

Approved by the Joint Prescribing & Medicines Management Group (JPG) December 2013, Review date: December 2015