Cinacalcet in Primary Hyperparathyroidism

Shared Care Guidelines

Introduction

Specialist Details	Patient Details
Name: _____ Location: _____	

Indication:
Cinacalcet is included in the County Durham & Darlington Formulary for patients with primary hyperparathyroidism in whom surgical parathyroidectomy is either not clinically appropriate, has failed, or is contraindicated.

Primary hyperparathyroidism is a common disorder characterised by chronically elevated of serum calcium and parathyroid hormone. Patients with moderate to severe disease can experience nephrolithiasis, loss of bone mineral density, neuromuscular weakness and neurobehavioural symptoms including easy fatigability and impaired cognitive function. Pararthyroidetomy is usually curative.

Cinacalcet is a calcimimetic which binds to calcium receptors on cells of the parathyroid hormone and serum calcium levels.

Reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated based on serum calcium levels, symptoms and end-organ damage, but in whom parathyroidectomy is either not clinically appropriate or is contraindicated.

Referral Criteria:
Patients stabilised on cinacalcet for primary hyperparathyroidism.

Dosage and administration:

Formulations & Strengths available	30mg, 60mg and 90mg film coated tablets
Usual Initiation & Maintenance Dose	Initial regimen: 30mg daily Maintenance: On direct instruction from hospital practitioner when dose established.
Usual Dose Range	Usually 30mg to 60mg bd (maximum dose of 90mg qds)
Likely Duration of Treatment	Lifelong

Specialist Responsibilities	• Initiation and provision of treatment with cinacalcet until patient is **stabilised** on the optimal dose. A minimum of 3 months treatment will be provided by the specialist. • Discussion with the patient/carer regarding the benefits, side effects and risks of treatment. • To make appropriate arrangements for 3 monthly monitoring of PTH and bone profile in secondary care (until transfer to GP) once a stable dose is established. • To review the patient every 6 months whilst on the drug to check benefit to symptoms, biochemical markers of hyperparathyroidism, adverse effect and compliance. If clinically relevant reductions in serum calcium are not maintained consideration should be given to discontinuing cincalcet. • Obtaining agreement of GP to participate in shared-care arrangement for cinacalcet therapy. • To detail clearly in the patient's notes the reason why the patient is unsuitable for surgery and clearly state these reasons in the correspondence to the GP when requesting that they participate in the shared-care arrangement. • Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment. • Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required. <u>Monitoring</u> Clinical Monitoring: Bone profile monitoring weekly until dose established, then bone profile and PTH, 3 monthly until transfer to GP. Safety Monitoring: Bone profile (ensure hypocalcaemia does not occur). Monitor side effects (non-specific, fortnightly).
GP Responsibilities	• Reply to request for shared-care as soon as practical (within 28 days). • Prescribe cinacalcet in accordance with the specialist's recommendations. • Adjust the dosage of cinacalcet on the advice of the specialist. • Monitor serum calcium every 3 months, if hypocalcaemia (serum calcium below 2.1mmol/l (8.4mg/dl) occurs stop cinacalcet and contact the specialist for further advice. • If clinically relevant reductions in serum calcium are not maintained advice should be sought from the specialist about whether treatment should be discontinued. • Stop treatment on advice of, or in consultation with, a specialist. • To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. • Report adverse events to specialist and MHRA. <u>Monitoring</u> Monitor serum calcium every 3 months.

Adverse Effects, Precautions and Contraindications

Adverse Effect Monitoring

Adverse Effects	Problem	Management
Common	Hypocalcaemia	Stop drug. Contact specialist immediately.
	Nausea and vomiting (10%)	Symptomatic relief. Contact specialist for advice.
Other Side Effects	Dizziness, paraesthesia, reduced testosterone levels, rash, myalgia, asthenia. Less common: seizures and dyspepsia	
Cautions / Contraindications	Liver Impairment	Use with caution in patients with hepatic impairment as plasma levels of cinacalcet are elevated 2-4 fold.
Renal Impairment	No additional caution required.	
Pregnancy and Breast Feeding	Cinacalcet should only be used in pregnancy if potential benefit justifies potential risk to the foetus. It is not known whether cinacalcet is excreted in human milk and if breast feeding, careful benefit risk assessment should be performed.	

See the manufacturers' summary of product characteristics (SPC) for a comprehensive list of other adverse effects

Common Drug interactions

Dose adjustment of Mimpara may be required if a patient receiving Mimpara initiates or discontinues therapy with a strong inhibitor (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or inducer (eg rifampicin) of the CYP34A enzyme
Cinacalcet is a strong inhibitor of CYP2D6. Dose adjustments of concomitant medicinal products may be required when Mimpara is administered with individually titrated, narrow therapeutic index substances that are predominantly metabolised by CYP2D6 (e.g., flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine)

Communication

Specialist to GP

- Obtaining agreement of GP to participate in shared-care arrangement for cinacalcet therapy (by sending a copy of this document).
- To detail clearly in the patient's notes the reason why the patient is unsuitable for surgery and clearly state these reasons in the correspondence to the GP when requesting that they participate in the shared-care arrangement.
- Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment.
- Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required.

GP to Specialist

- Reply to request for shared-care as soon as practical (within 28 days).
- To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment.

Contact names and details

If you have any concerns regarding an individual patient, contact the Specialist or secretary.

Details

Date approved by APC: 3rd July 2014
Date for Review: 3rd July 2017

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