### Shared Care Guideline

**DRUG:** Cinacalcet (Adults)

**Introduction:**
Patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated.

**Licensing Information:**
See SPC for full list of licensed indications. The above is a licensed indication.

**Formulations:**
30mg, 60mg and 90mg tablets

**Dosage & administration:**
Cinacalcet is administered orally at a starting dose of 30mg twice daily, with the dose being titrated upwards according to response. Typical maintenance doses vary and should be in line with specialist advice. Maximum dose 90mg four times a day. Take with or shortly after food.

**Contraindications & Warnings:**

**Contraindications**
- Hypersensitivity to cinacalcet or any of the excipients

**Cautions**
- Galactose intolerance
- Hypocalcaemia
- Hepatic impairment – close monitoring is required
- Patients with seizures – the seizure threshold is lowered by significant reductions in serum calcium levels
- Hypotension – idiosyncratic cases of hypotension have been reported in patients with impaired cardiac function
- Heart failure – idiosyncratic cases of worsening heart failure have been reported in patients with impaired cardiac function
- Pregnancy - There are no clinical data from the use of cinacalcet in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Any planned or unplanned pregnancy should be discussed with the specialist.
- Breast feeding - It is not known whether cinacalcet is excreted in human milk and patients should therefore be advised not to breast feed.

**Interactions:**
- **Strong Inhibitors of CYP3A4 enzyme** – eg ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir. Cinacalcet levels may be increased and dose adjustment may be required
- **Strong inducers of CYP3A4 enzyme** – eg rifampicin. Cinacalcet levels may be reduced and dose adjustment may be required
- **Strong Inhibitors of CYP1A2 enzyme** – eg fluvoxamine, ciprofloxacin. Cinacalcet levels may be increased and dose
**Smoking** – increases clearance of cinacalcet as it induces the CYP1A2 enzyme. Dose adjustment of cinacalcet may be required if a patient starts or stops smoking.

**Drugs metabolised by CYP2D6 enzyme** – eg flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine and tamoxifen. Cinacalcet is a strong inhibitor of enzyme CYP2D6 and may increase the level of these drugs, so dose adjustment may be required. **BNF advised to avoid concomitant use with tamoxifen.**

If there are any concerns regarding drug interactions and dose changes, contact the specialist team.

For full list see SPC at [www.medicines.org.uk/EMC](http://www.medicines.org.uk/EMC)

### Adverse Effects:

**Gastrointestinal side effects** - nausea and vomiting commonly reported but generally mild/moderate in nature and usually transient. Anorexia is also commonly reported. Less commonly diarrhoea and dyspepsia

**Central nervous system** - commonly dizziness, paraesthesia and uncommonly seizures  (see above under warnings)

**Cardiac** – isolated reports of hypotension and/or worsening heart failure in patients with impaired cardiac function. Also isolated reports of QT prolongation and ventricular arrhythmia secondary to hypocalcaemia.

**Allergic reactions** – hypersensitivity reactions are uncommon

**Rashes** – common

**Asthenia** – common

**Hypocalcaemia** – a reduction in serum calcium is part of the pharmacological effect of cinacalcet, however, symptomatic hypocalcaemia may occur and be responsible for isolated reports of arrhythmias, seizures. More common symptoms would be paraesthesia, myalgia, cramping

For full list see SPC at [www.medicines.org.uk/EMC](http://www.medicines.org.uk/EMC)

### Responsibilities of the specialist initiating treatment:

**General:**

- To assess the suitability of the patient for treatment.
- To ensure that the patient/carer has received counselling and understands the therapy, its benefits, limitations, continued monitoring (where applicable), adverse effects, and is aware of actions to take if adverse effects are suspected.
- Inform the GP of the information provided to the patient.
- To review the patient at agreed intervals and copy any relevant results to the GP.
- Carry out disease and drug monitoring as listed below.
- Formally hand over to GP by letter and patient informed - send a copy.

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Name: CINACLCET in primary hyperparathyroidism Shared Care Guideline
Version: 1
Issue Date: April 2014
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Page 2 of 5
(either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care.

**Prescribing:**
- Issue all prescriptions until a stable dose has been reached and the specialist team are satisfied that it is appropriate to share care.

**Disease & drug monitoring:**
- Baseline biochemical monitoring will be undertaken by the specialist in addition to all ongoing routine blood monitoring as described as part of the diagnosis and management of the condition (unless specifically agreed with the GP)

| Serum calcium | 1 week after initiation or dose adjustment. After maintenance dose has been established, levels should be measured every 6 months (as per local policy) or sooner, if there are symptoms of hypo or hypercalcaemia or concern regarding hydration status |

- Discuss shared care arrangement with patient.
- Support and advise GPs as required.
- Assess response to treatment and advise the GP on any dose adjustments required as clinically appropriate, including discontinuation of treatment.

**General and Prescribing:**
- Reply to the request for shared care within 2 weeks of receipt of the Consultant letter.
- Prescribe according to the dose advised by the specialist. The GPs will be typically asked to take up the prescribing of cinacalcet once a stable dose has been reached.
- Notify Consultant if treatment with cinacalcet is discontinued.
- Ensure there are no drug interactions with any other medications initiated in primary care.

**Disease & drug monitoring:**
- The Consultant will undertake routine blood monitoring unless specifically indicated and agreed e.g the patient is too infirm to attend out-patient clinics. In those circumstances advice on monitoring would be provided. GP to monitor for side effects, drug interactions etc
- Refer back to the Specialist if the patient’s condition deteriorates.
- Stop treatment on the advice of the specialist.
- Urgent drug discontinuation/ referral to specialist as clinically appropriate e.g presence of symptomatic hypocalcaemia.
- Identify adverse effects if the patient presents with any signs and liaise with the hospital Specialist where necessary. Report adverse effects to the Specialist and where appropriate to the Commission on Human Medicines/MHRA (Yellow Card scheme).

Unless otherwise stated by the secondary care Specialist, apply the following monitoring frequencies following handover from secondary care:
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<th>At consultations</th>
<th>Ask about any adverse effects and inform the Specialist team as clinically appropriate</th>
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Discontinue cinacalcet and seek advice from initiating team if adverse effects are clinically significant

Responsibilities of the Patient / Carer:

**General:**
- Report any possible side effects to their GP.
- Ensure they have an adequate supply of medication.
- Attend appointments.

**Disease & drug monitoring:**
As above – contact GP or initiating team if side effects develop (see adverse effects) and attend appointments including those for routine blood tests/investigations

Communication:

**Specialist to GP:**
- The specialist will inform the GP when they have initiated cinacalcet and when there are any subsequent changes in treatment – standard clinic letter.
- Send a copy (either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care.
- Inform the GP of the information provided to the patient

**GP to Specialist:**
- To reply to the request for shared care within 2 weeks of receipt of the Consultant letter.
- Irrespective of whether you accept prescribing responsibility or not, you should inform the consultant of relevant medical information regarding the patient and any changes to the patient’s medication regime irrespective of indication.
- Notify Consultant if treatment with cinacalcet is discontinued.

Contact names & details:
If you have any concerns regarding individual patients, see consultant letter for medical contact details or contact one of the following:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Location</th>
<th>Telephone /Bleep /Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>York Endocrinology secretaries</td>
<td>Dr Thow, Dr Jennings, Dr Jayagopal</td>
<td>01904 725604</td>
</tr>
<tr>
<td>York Endocrinology specialist nurse</td>
<td>Ottilia Buch</td>
<td>01904 726807</td>
</tr>
<tr>
<td>Scarborough Endocrinology secretaries</td>
<td>Dr David Humphriss, Dr Tadeusz Pawlak</td>
<td>01723 342036</td>
</tr>
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Cost:
- Cinacalcet 30mg : £125.75 / 28 tablets  (Drug Tariff accessed Feb 2014)
- Cinacalcet 60mg : £231.97/28 tablets   (BNF March 2014)
- Cinacalcet 90mg : £347.96/28 tablets   (BNF March 2014)
References:

- Cinacalcet SPC, last updated on the eMC: 24/10/2013
- BNF 65

Document Control:

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

The original Microsoft Word file of this document is located on:
York Teaching Hospital NHS Foundation Trust Pharmacy Department X:\MEDICINES INFORMATION\Shared Care Guidelines\Approved Shared Care Guidelines\CINACALCET in primary hyperparathyroidism Shared Care Guideline V1.0

Shared Care Guidelines are also available electronically via http://www.yorkandscarboroughformulary.nhs.uk/

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