Shared Care Guidelines for the Use of Cinacalcet in Primary Hyperparathyroidism

September 2016

This guidance has been prepared and approved for use in Gateshead, Newcastle, North Tyneside and Northumberland in consultation with the Primary and Secondary Care NHS trusts.

This guideline sets out details of the respective responsibilities of GPs and specialist services within shared care prescribing arrangements and is intended to provide sufficient information to enable GPs to prescribe cinacalcet in patients with primary hyperparathyroidism.

Further copies are available from:

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An electronic version of this document can also be viewed / downloaded from
the North of Tyne Area Prescribing Committee’s Website
http://www.northoftyneapc.nhs.uk

<table>
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<tr>
<th>Approved on behalf of the</th>
<th>Name</th>
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<tbody>
<tr>
<td>North of Tyne and Gateshead Medicines Guidelines and Use Group</td>
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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 neurobehavioral symptoms including easy fatigability and impaired cognitive function. Parathyroidectomy is usually curative.

Cinacalet is the first of a new class of drugs, the calcimimetics, that bind to calcium receptors on cells of the parathyroid gland, increasing their sensitivity to extracellular calcium reducing secretion and lowering parathyroid hormone and serum calcium levels.

Referral Criteria
Patients stabilised on cinacalcet for primary hyperparathyroidism.

Specialist / Secondary Care Responsibilities
- Initiation and provision of treatment with cinacalcet until patient is stabilised on the optimal dose.
- Initiation of vitamin D (800iu daily) therapy in patients who are not vitamin D insufficient at baseline replete e.g. (< 50 mol/L). N.B. vitamin D loading regimens with high-strength colecalciferol should not be used unless parathyroid surgery is imminent.
- Discussion with the patient/carer regarding the benefits, side effects and risks of treatment.
- To make appropriate arrangements for 3-4 monthly monitoring of PTH and bone profile in secondary care 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.
- Obtaining agreement of GP to participate in shared-care arrangement for cinacalcet therapy.
- To detail clearly in the patient’s notes the reasons 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.

General Practitioner’s 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 2 months, if hypocalcaemia occurs stop cinacalcet and contact the specialist for further advice.
- 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 CSM.

**Joint Responsibilities**

- In the context of less severe baseline hypercalcaemia (2.6 – 2.8 mmol/L) to make a clinical judgement within 6 months as to whether normalization of serum calcium with cinacalcet has resulted in meaningful clinical outcomes, such as improved cognitive function/reduced confusion, reduced frequency of hospitalisations, or reduction in hypercalcaemia-related symptoms (constipation, dyspepsia, polyuria/polydipsia).

- In the event that such clinical improvements have not been seen and, thus, the only documented benefit has been biochemical, GP and specialist to consider withdrawal of therapy, with continued monitoring and, in the event of any deterioration, consideration of restart.
## Drug
Cinacalcet

## Indication
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.

## Formulations and strengths available
30 mg, 60 mg and 90 mg film coated tablets.

## Usual initiation and maintenance dose
Initial regimen: 30mg daily
Maintenance: On direct instruction from hospital practitioner when dose established

## Usual dose range
Usually 15mg to 60mg bd (maximum dose of 90mg qds)

## Likely duration of treatment
Lifelong

## Cost (DM+D Dec 2016)
28 x 30mg = £125.75, 28 x 60mg = £231.97, 28 x 90mg = £347.96

## Adverse Effects

<table>
<thead>
<tr>
<th>Problem</th>
<th>Management</th>
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</thead>
<tbody>
<tr>
<td><strong>Common</strong></td>
<td></td>
</tr>
<tr>
<td>Hypocalcaemia</td>
<td>Stop drug. Contact specialist</td>
</tr>
<tr>
<td></td>
<td>immediately.</td>
</tr>
<tr>
<td>Nausea and vomiting (5%)</td>
<td>Symptomatic relief. Contact specialist for advice.</td>
</tr>
<tr>
<td><strong>Other Side Effects</strong></td>
<td>Dizziness, paraesthesia, reduced testosterone levels, rash, myalgia, asthenia.</td>
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<tr>
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<td>Less common: seizures and dyspepsia</td>
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## 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 know whether cinacalcet is excreted in human milk and if breast feeding, careful benefit risk assessment should be performed.

## Drug Interactions
Dose adjustment of cinacalcet may be required if a patient initiates or discontinues therapy with a strong CYP3A4 Inhibitor of (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or inducer (e.g. rifampicin) of this enzyme. For details of other interactions please refer to the current cinacalcet SPC on www.medicines.org.uk

## Monitoring

### Initial investigations
Secondary Care

**Clinical monitoring:** Bone profile monitoring weekly until dose established, then bone profile and PTH, 3-4 monthly. Vitamin D levels.

**Safety monitoring:** Bone profile (ensure hypocalcaemia does not occur). Monitor for side effects (non-specific, fortnightly).

**GP**
Monitor serum calcium every 2 months
Shared Care Request/Confirmation

- Consultant/Specialist Nurse to complete first section of form and send to patient’s GP.
- GP to complete second section of form and return to hospital consultant within 28 days.

A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

Patient Details (use hospital label if preferred)

Name .................................................................

Address .............................................................

Postcode ....................................................... Sex ......


Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement:

Drug Name ......................................................... Dose ........ Frequency .................................

Other Information (if appropriate) .................................................................

................................................................................................................................................

Signed (Hosp. Dr / Specialist Nurse) ....

Name (print) .................................................. Date ..................................................

To be completed by GP

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient

Or

I ACCEPT the proposed shared care arrangement with the caveats below

Or

I DO NOT ACCEPT the proposed shared care arrangement for this patient

My caveats / reason(s) for not accepting include:

................................................................................................................................................

................................................................................................................................................

Signed ......................................................... Name (print) .............................................. Date ........................

(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the hospital consultant and the patient’s GP