

North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Cinacalcet

Shared Care Guidance

For the management of complex primary hyperparathyroidism in adults

<p>Introduction</p>	<p>Formulary approved 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. It is not normally commissioned if serum calcium concentration is <2.85 mmol/L, further information about approved criteria has been published by NHSE¹.</p> <p>Dose Initiation – 30mg daily, maintenance is usually 15mg to 60mg twice daily (on direct instruction from hospital practitioner when dose established)</p> <p>Maximum Dose 90mg four times a day</p> <p>Duration Lifelong</p> <p>Formulary Preparations 30mg, 60mg and 90mg film coated tablets</p>
<p>Specialist Responsibilities</p>	<ul style="list-style-type: none"> • Initiation and provision of treatment with cinacalcet until patient is stabilised on the optimal dose, at a minimum 3 months from initiation of therapy • Initiation of vitamin D (800iu daily) therapy in patients who are vitamin D deficient at baseline (e.g., <50nmol/L). <i>N.B.</i> 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 6-12 monthly monitoring of bone profile in secondary care once a stable dose has been established • To review the patient every 6 months whilst on the drug to check benefit to symptoms, biochemical markers of hyperparathyroidism, adverse effects, and compliance • Obtaining agreement of GP to participate in shared care arrangement for cinacalcet therapy

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	<ul style="list-style-type: none"> 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 agreement 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 effect, as required 													
<p>GP Responsibilities</p>	<ul style="list-style-type: none"> 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 Continue to prescribe vitamin D (800iu daily) at the direction of the specialist if necessary Monitor serum calcium every 2-3 months, and within 1-2 weeks of any dose change; if hypocalcaemia occurs, stop cinacalcet and contact the specialist for further advice Stop treatment on the 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 any adverse events to the specialist and submit a Yellow card report to the MHRA 													
<p>Adverse Effects, Use in pregnancy, Contraindications</p>	<p>Contraindications Liver impairment – use with caution in patients with hepatic impairment as plasma levels of cinacalcet are elevated 2-4 fold.</p> <p>Pregnancy and breastfeeding 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 breastfeeding, careful risk benefit assessment should be performed.</p> <p>Adverse Effects</p> <table border="1" data-bbox="496 1585 1497 1957"> <thead> <tr> <th></th> <th>Problem</th> <th>Management</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Common</td> <td>Hypocalcaemia</td> <td>Stop drug. Contact specialist immediately</td> </tr> <tr> <td>Nausea and vomiting (5%)</td> <td>Symptomatic relief. Contact specialist for advice</td> </tr> <tr> <td rowspan="2">Other side effects</td> <td colspan="2">Dizziness, paraesthesia, reduced testosterone levels, rash, myalgia, asthenia</td> </tr> <tr> <td colspan="2">Less common: seizures and dyspepsia</td> </tr> </tbody> </table>		Problem	Management	Common	Hypocalcaemia	Stop drug. Contact specialist immediately	Nausea and vomiting (5%)	Symptomatic relief. Contact specialist for advice	Other side effects	Dizziness, paraesthesia, reduced testosterone levels, rash, myalgia, asthenia		Less common: seizures and dyspepsia	
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<p>Common Drug Interactions</p>	<p>Dose adjustment may be required if a patient starts or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or inducer (e.g., rifampicin). For the same reason dose adjustment is required if smoking is started or stopped during treatment. For details of other interactions please refer to the current cinacalcet SPC at www.medicines.org.uk.</p>
<p>Communication/Contact Details</p>	<p>Specialists Mon – Fri 09:00 – 17:00</p> <p>Gateshead Health NHS FT: Dr K R Narayanan Consultant Physician and Endocrinologist 0191 4452856 k.narayanan1@nhs.net</p> <p>Newcastle Upon Tyne NHS FT: Dr Richard Quinton 0191 2824635 Dr Yaasir Mamoojee 0191 2820114 Dr Anna Mitchell 0191 2825299 Dr Catherine Napier 0191 2820590 Prof Simon Pearce 0191 2824636</p> <p>Northumbria HCFT: Dr Stuart MA Bennett, Consultant Physician (Endocrinology & Diabetes), 0191 2932516 stuart.bennett@nhct.nhs.uk</p> <p>North Cumbria Integrated Care NHS FT: Dr Louise Overend 01228 814949 Dr Muhammad Asam 01228 814140 Dr Chandi Idampitiya 01946 523010</p>

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

Private and Confidential

Cinacalcet - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

Specialist Prescriber				
Department				
Hospital				
Telephone				
Patient details (use hospital label if preferred)				
Name				
Address				
Postcode				
NHS or Hosp reg no		Male / Female	DoB	

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement				
Drug Information – Cinacalcet				
Formulation		Dose		Frequency
Indication – For the management of complex primary hyperparathyroidism in adults				
Other information (if appropriate)				
Signed (Specialist Prescriber)		Name (Print)		Date

To be completed by GP			Please tick one box	
I ACCEPT the proposed shared care arrangement for this patient			<input type="checkbox"/>	
I ACCEPT the proposed shared care arrangement with the caveats below			<input type="checkbox"/>	
I DO NOT ACCEPT the proposed shared care arrangement for this patient			<input type="checkbox"/>	
My caveats/reason(s) for not accepting include:				
Signed		Name (print)		Date

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP

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