North Central London
Joint Formulary Committee

Shared Care Guideline
Cinacalcet
Treatment of Primary Hyperparathyroidism

Dear Primary Care Prescriber.

The information in this shared care guideline has been developed in consultation with Primary Care, with agreement that shared care is appropriate.

Sharing of care assumes communication between the specialist, primary care prescriber and patient. The intention to share care should be explained to the patient by the specialist clinician when treatment is initiated. It is important that patients are consulted about treatment and are in agreement with it.

Further information on shared care, including out of area referrals, can be found in the NCL Interface Prescribing Guidance.

Shared Care Guideline

Indication	As per local formulary agreement, cinacalcet is recommended for the reduction of hypercalcaemia in 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. This is a licensed use of cinacalcet. Treatment should be initiated by a clinician with expertise in the treatment of primary hyperparathyroidism who will consider contraindications (link: BNF & SPC) and cautions (link: BNF & SPC) for use.
Shared Care criteria	Once a patient has been stabilised on treatment 3 months, a shared care arrangement with you will be requested.
Dose	**Initial stabilisation (by specialist team):** The recommended starting dose is 30mg orally once or twice a day. The dose may be reduced to 15mg according to specialist recommendation. The dose of cinacalcet may be titrated every 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 reduce serum calcium concentration to or below the upper limit of normal. **Maintenance dose:** Usual maintenance dose is 30-60mg once or twice daily. Maximum licensed dose: 90mg orally four times a day, with or after food. **Conditions requiring dose adjustment** Further information about prescribing in elderly and patients with hepatic impairment can be found here (link: BNF & SPC).

<table>
<tr><td>Duration of treatment</td><td colspan="3">Until parathyroidectomy or potentially lifelong</td></tr>
<tr><td>Stopping criteria and treatment discontinuation</td><td colspan="3">Patient intolerance or if adjusted serum calcium < 2.4mmol/L on minimum cinacalcet dose – discuss with specialist.</td></tr>
<tr><td>Baseline monitoring (by specialist)</td><td colspan="3"><u>Baseline monitoring:</u>
• Vitamin D > 50nmol/L
• Parathyroid hormone (PTH) (for diagnosis but not for ongoing monitoring)
• Bone profile
• Urea and electrolytes</td></tr>
<tr><td rowspan="5">Ongoing monitoring
(initially by specialist; in stable patients may be requested to be monitored by primary care clinician)</td><td>Test:</td><td>Frequency</td><td>Action if out of range</td></tr>
<tr><td rowspan="3">Adjusted calcium (mmol/L)</td><td rowspan="3">3-4 monthly

6 monthly for patients with stable serum calcium, as per primary care prescriber discretion</td><td><2.4: Stop/reduce cinacalcet and request advice from Endocrinologist</td></tr>
<tr><td>2.4 – 2.7*: Dose adequate – continue treatment
Aim for upper end of serum Ca range</td></tr>
<tr><td>>2.7*: Consider dose increase or request advice from Endocrinologist</td></tr>
<tr><td colspan="3">* The goal of treatment would normally be to reduce the calcium to a level that would no longer cause symptoms to the patient, or certainly no lower than the upper-normal range. Note that in consultation with the endocrinologist, corrected calcium levels of <2.85 may be considered acceptable.</td></tr>
<tr><td>Follow up arrangements</td><td colspan="3">Patients are followed up in specialist clinic annually. Patients stable on long-term treatment and are not surgical candidates for parathyroidectomy may be discharged to primary care. Specialists will always be available for guidance e.g. via Advice and Guidance.

The specialist may conduct additional investigations as required e.g. Parathyroid hormone (PTH) and Vitamin D annually, but variations in PTH levels may not be clinically significant.</td></tr>
<tr><td rowspan="4">Adverse effects and management

For a full list of adverse effects, please refer to the (link: BNF & SPC)

Healthcare professionals are asked to report any suspected adverse reactions to the MHRA via the Yellow Card Scheme.</td><td>Adverse effect</td><td>Frequency</td><td>Action for GP</td></tr>
<tr><td>Worsening heart failure, QT prolongation ,and ventricular arrhythmia secondary to hypocalcaemia</td><td>Unknown</td><td>Stop cinacalcet and contact endocrinologist.</td></tr>
<tr><td>Gastrointestinal e.g. Nausea, vomiting, decreased appetite, dyspepsia
Diarrhoea
Abdominal pain
Constipation</td><td>Very Common</td><td>Symptomatic management, or trial reduced dosage</td></tr>
<tr><td>Hypocalcaemia
Hyperkalaemia
Dizziness
Paraesthesia
Asthenia
Headache</td><td>Common</td><td>Please stop cinacalcet, or reduce dosage, and contact endocrinologist.</td></tr>
<tr><td>Advice to patients and carers</td><td colspan="3">The patient should be advised to report any of the above signs or symptoms to their primary care prescribers/specialist without delay.</td></tr>
</table>

	Attend blood tests 3-6 monthly.
Resources and key references	Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults. NHS England: 16034/P July 2016. Available at : https://www.england.nhs.uk/wp-content/uploads/2017/06/ccp-cinacalcet-complex-primary-hyperparathyroidism-adults.pdf Ng CH, Chin YH, Tan MHQ, Ng JX, Yang SP, Kiew JJ, Khoo CM. Cinacalcet and primary hyperparathyroidism: systematic review and meta regression. Endocr Connect. 2020 Jul;9(7):724-735. Joint Formulary Committee. *British National Formulary*. London: BMJ Group and Pharmaceutical Press. Cinacalcet. Available at https://bnf.nice.org.uk/ Summary of Product Characteristics – Mimpara (cinacalcet). Amgen Ltd. [date of revision of the text Jan 2021]; available at https://www.medicines.org.uk/emc/product/5599/smpc#about-medicine Package Information Leaflet – Mimpara (cinacalcet). Amgen Ltd. [date of revision of the text Sept 2021]; available at https://www.medicines.org.uk/emc/files/pil.5599.pdf Patient information leaflet 'Primary Hyperparathryoidism'. Parathyroid UK. Available at https://parathyroiduk.org/wp-content/uploads/2018/10/Hyperparathyroidism-Leaflet-DL-2-31_10.pdf NICE Clinical Guideline 132: Hyperparathyroidism (primary): diagnosis, assessment and initial management. Available at https://www.nice.org.uk/guidance/ng132

Contact Details

North Middlesex University Hospital NHS Trust	NMUH Trust Switchboard: 020 887 7000 Endocrinology consultant: #6699 Endocrinology secretaries email: northmid.endocrine@nhs.net Endocrinology secretaries phone number: 0208 887 2287 Pharmacy Medicines Advice telephone: 0208 887 2417

	Pharmacy Medicines Advice email: nmu-tr.medicinesinformation@nhs.net
Royal Free London NHS Foundation Trust	RFL Trust Switchboard: 020 3758 2000 RFH Switchboard: 020 7794 0500 Endocrinology secretaries at Barnet and Chase Farm Hospitals: rf-tr.barnetendodiabadmin@nhs.net Endocrinology secretaries at Royal Free Hospital: Rf.diabendocrineadmin@nhs.net Pharmacy Medicines Advice: Rf.medicinesadvice@nhs.net 0207 830 2983

Document control

Date	Version	Amendments
25/06/2024	1.0	New document developed in collaboration with NMUH and RFL clinical teams

Groups / Individuals who have overseen the development of this guidance:	Dr Bernard Freudenthal (RFL) Ms Georgina Glass (RFL) Dr Sajid (NMUH) NCL ICB Medicines Optimisation team
Groups which were consulted and have given approval:	NCL consultants and specialist pharmacists NCL GPPA NCL LMC NCL Shared Care Group
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Equality impact assessment:	Low
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Review date:	08/10/2027

Appendix 1: xxx transfer form: from [Trust] to GP practice

Section A: to be completed by secondary care *Send to practice*

This document is to request the shared care pathway of your patient and comprises an agreement betweer the GP and named consultant. The patient will continue to be seen by the named consultant as regular foll up.

Fix address label here (ensure NHS Number inc.)	Clinic stamp *or give details below*

Department			
Clinic phone			
Consultant		Email	
Indication for prescription			
Drug prescribed			
Date	Drug started	Current dose	
Relevant conditions			
Monitoring variations			
Date next blood test		Next disease review due in	months' time.

Section B: [Accept Shared Care] to be completed by practice

*Send back **FAO referring consultant** above*

The above patient has been accepted into our monitoring service.

Practice date for next blood test		Practice stamp
Signed / Designation		
Date		

Section B: [Reject Shared Care] to be completed by practice

*Send back **FAO referring consultant** above*

The above patient has not been accepted into our monitoring service.

Reason		Practice stamp
Signed / Designation		
Date		