Shared Care Agreement: Cinacalcet for the management of primary and secondary hyperparathyroidism

This Shared Care Protocol sets out details for the sharing of care for patients prescribed oral Cinacalcet. This protocol is for use within adult patients (aged 18 years and over) with primary hyperparathyroidism and secondary hyperparathyroidism with chronic renal failure.

It should be read in conjunction with the latest Summary of Product Characteristics (SPC) available at electronic medicines compendium.

As outlined in NHS England Guidance 2018 "Responsibility for Prescribing between Primary & Secondary/Tertiary Care. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the primary care clinicians concerned and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the consultant and primary care clinician concerned. The primary care clinician may accept or decline shared care. If shared care is declined the primary care clinician practice must discuss the reason for refusal with the consultant within 14 days. Where appropriate, the clinical responsibility will then remain with the consultant.

Introduction

This shared care guideline sets out details to support the transfer of responsibility for prescribing Cinacalcet for any of the indications listed in section 2, from specialist to primary care. For further information please click on the links below:
British National Formulary
electronic medicines compendium

Document Ratification Table

Ratification Process	Details
Authored by:	Cambridgeshire and Peterborough Integrated Care System
Ratified by:	Cambridgeshire and Peterborough Joint Prescribing Group
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Version number:	2

The content of this shared care protocol was correct as of May 2025. As well these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

Hospital Specialist

- Initiate Cinacalcet until serum calcium level becomes acceptable.
- Send a letter to the primary care clinician requesting shared care for the patient.
- Inform the primary care clinician after each clinic attendance, including any change to treatment or monitoring and patients who do not attend clinic appointments.
- To provide any advice to the patient/carer when requested.
- Encourage patients and those with caring responsibilities to access their records via the NHS app and hospital electronic platforms, and to be actively engaged in the review process.
- Advise primary care clinician on review, duration or discontinuation of treatment where necessary.
- Monitor smoking status of patient and review dosing if this changes (smoking reduces plasma levels of Cinacalcet). Explain the effect of smoking on therapy and encourage smokers to quit.
- Evaluate any reported adverse effects by primary care clinician or patient.
- Arrange blood tests during the initiation of cinacalcet whilst being prescribed by the hospital consultant.
- Organise the supply of medication to the patient, including patients who cannot regularly attend the outpatient pharmacy.
- Provide a telephone follow up service and phone the patient every 12 months after transitioned to primary care clinician prescribing and escalate to hospital consultant if necessary, such as when the patient cannot be reached despite multiple attempts.

Primary care responsibilities

- Refuse the request for shared care in writing within 14 days. Acceptance will be assumed if no response was received within this time period.
- Prescribe cinacalcet at the dose advised by the hospital specialist.
- Check serum calcium every three months and seek advice from the hospital specialist if calcium falls below 2.7mmol/L.
- Report any adverse events to the hospital specialist and request advice from the hospital specialist when necessary.

- Inform hospital specialist if any new medication that may interfere with cinacalcet is commenced. Please see section 6 for examples.
- Monitor smoking status of patient and seek guidance from specialist if this changes (smoking reduces plasma levels of Cinacalcet). Explain the effect of smoking on therapy and encourage smokers to quit, supporting the consultant/ specialist nurse in achieving this.

Patient and/or carer responsibilities

- Report to the hospital specialist or primary care clinician if they do not have a clear understanding of their treatment.
- Patients must not exceed the recommended dose.
- Patients must attend their appointments (face to face or virtual), as well as blood tests.
- Must inform other clinical staff that they are receiving treatment.
- Report any adverse effects to the hospital specialist or primary care clinician.
- Attempt to cease smoking.
- Patient must notify any change in smoking status to primary care clinician/ specialist immediately.

1. Background

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Cinacalcet mimics the action of calcium on the parathyroid cells, suppressing PTH production, and is used for both primary and secondary hyperparathyroidism.

Primary hyperparathyroidism is a condition caused by over-activity of one or more of the four parathyroid glands and is a common endocrine condition. It is associated with increases in parathyroid hormone (PTH) levels and an increase in calcium and phosphate metabolism.

For patients with chronic renal failure (CRF), secondary hyperparathyroidism (SHPT) is a condition that develops progressively and is associated with increases in parathyroid hormone levels and derangements in calcium and phosphate metabolism.

2. Indications

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- Primary hyperparathyroidism
- Secondary hyperparathyroidism for patients with chronic renal failure

3. Locally agreed off-label use

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The initial dose of cinacalcet we recommend for most patients with primary hyperparathyroidism (30mg once daily) is below the licensed dose (30mg twice daily). Most patients started on this dose do not require escalation to 30mg twice daily. Patients with very high baseline PTH (iPTH >30pmol/L) we recommend starting at full licensed dose 30mg twice daily.

Ref: Bell D, Hale J, Go C, et al. A single-centre retrospective analysis of cinacalcet therapy in primary hyperparathyroidism. Endocrine Connections. 2021;10(11):1435-1444.

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypocalcaemia.
- Hypersensitivity to the active substance or any of the excipients.
- Patients below the age of 18 years, as safety and efficacy have not been established.
- Cinacalcet should only be used in pregnancy if the potential benefit justifies the potential risk to the foetus. It should not be used whilst breast-feeding.

Cautions:

- Cinacalcet is not at effective at reducing the end organ damage caused by PHPTH including reduced bone mineral density leading to osteopenia and osteoporosis and hypercalcuria which can cause renal stones. These risks must be managed separately.
- Significant reductions in serum calcium levels can lead to paraesthesias, myalgias, cramping, tetany and convulsions, and QT-interval prolongation and ventricular arrhythmias.
- Therefore, cinacalcet is cautioned in patients with known congenital long QT syndrome or patients receiving medicinal products known to cause QT prolongation.
- A dynamic bone disease may develop if PTH levels are chronically suppressed below approximately 1.5 times the upper limit of normal with the iPTH assay. If PTH levels decrease below the recommended target range in patients treated with Cinacalcet, the dose of Cinacalcet and/or vitamin D sterols should be reduced or therapy discontinued.
- Moderate-severe hepatic impairment (Child-Pugh classification) due to the potential for 2 to 4-fold higher plasma levels of cinacalcet and risk of hypocalcaemia.
- The threshold for seizures is lowered by significant reductions in serum calcium levels.

5. Initiation and ongoing dose regimen

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- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

- Cinacalcet will be commenced by the specialist at a dose of 30mg, taken orally, once daily.
- Patients with primary hyperparathyroidism and a baseline iPTH >30pmol/L may start at a higher dose 30mg, taken orally, twice daily.

For primary hyperparathyroidism:

- The dose will be adjusted as required to achieve the calcium level within the target range<2.7mmol/L.
- If calcium has not fallen by a minimum of 0.25mmol/L in the first eight weeks the dose of cinacalcet should be increased to 30mg, taken orally, twice daily.

For secondary hyperparathyroidism:

- The dose can be titrated every two to four weeks to a maximum dose of 180mg, aiming to achieve a target PTH level 2-9 times the upper limit of normal.

The initial stabilisation period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

For primary hyperparathyroidism:

- The usual daily dose of cinacalcet is 30mg-180mg in divided doses but can go up to 360mg per day (90mg four times a day).

For secondary hyperparathyroidism:

- The usual dose of cinacalcet is 30mg-180mg, taken orally, once daily.

The initial maintenance dose must be prescribed by the initiating specialist. Shared care and prescribing can only be transferred once a stable dose has been established.

Conditions requiring dose adjustment:

- If a patient receiving cinacalcet initiates or discontinues therapy with a strong inhibitor (e.g. azoles, telithromycin, ritanovir) or inducer (e.g. rifampicin) of CYP3A4.

Changes in smoking status, as smoking induces CYP1A2 which increased the clearance of cincacalcet.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Cinacalcet 30mg tablets Cinacalcet 60mg tablets Cinacalcet 90mg tablets
Administration details:	Cinacalcet should be swallowed whole, with food or shortly after a meal as this increases bioavailability. Tablets should not be chewed or crushed.
Other important information:	The switch from etelcalcetide to Cinacalcet and the appropriate wash out period has not been studied in patients. In patients who have discontinued etelcalcetide, Cinacalcet should not be initiated until at least three subsequent haemodialysis sessions have been completed, at which time serum calcium should be measured. Ensure serum calcium levels are within the normal range before Cinacalcet is initiated.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

- Concurrent administration of other medicinal products known to reduce serum calcium may result in an increased risk of hypocalcaemia.
- Dose adjustment may be required if a patient receiving cinacalcet initiates or discontinues therapy with a strong inhibitor (eg azole antifungal, telithromycin, ritonavir) or inducer (eg rifampicin) of CYP3A4.
- Smoking induces CYP1A2 and clearance of cinacalcet is higher in smokers than non-smokers. The effect of CYP1A2 inhibitors (eg fluvoxamine, ciprofloxacin) is not known but may impact on dosage if these drugs are discontinued or initiated.
- Cinacalcet is a strong inhibitor of CYP2D6. Dose adjustments of concomitant medicinal products may be required when cinacalcet is administered with individually titrated, narrow therapeutic index substances that are predominantly metabolised by CYP2D6 (e.g. flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine).

Further information about dose and administration, adverse affects, cautions, contraindications and interactions can be found in the Summary of Product Characteristics.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- Serum calcium concentration

Initial monitoring and at dose change:

For primary hyperparathyroidism:

- Serum calcium concentration 2 to 4 weeks after initiation, or following dose adjustment by hospital specialist.

For secondary hyperparathyroidism:

- PTH 2 to 4 weeks after initiation or following dose adjustment.
- Serum calcium concentration weekly for one month after initiation or dose adjustment

Ongoing monitoring:

For primary hyperparathyroidism:

- Serum calcium concentration every 2 to 4 weeks until it is within range on a stable dose.

For secondary hyperparathyroidism:

- Serum calcium concentration every three months
- PTH every three months
- Phosphate level monthly.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

This section is **only applicable for primary hyperparathyroidism.**

Monitoring	Frequency
• Serum calcium concentration	Every three months. Primary care clinician should seek advice from the hospital specialist if calcium rises >2.7mmol/L, or falls <2.4mmol/L

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard.

For information on incidence of ADRs see relevant summaries of product characteristics.

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.

Result	Action for primary care
Immune system disorders **Common:** • Hypersensitivity reactions	**Refer back to specialist services**
Metabolism and nutrition disorders **Common:** • Anorexia • Decreased appetite	**Refer back to specialist services**
Nervous system disorders **Common:** • Seizures • Dizziness • Paraesthesia • Headache	**Refer back to specialist services**
Cardiac disorders **Unknown frequency:** • Worsening heart failure • QT prolongation and ventricular arrhythmia secondary to hypocalcaemia	**Refer back to specialist services**
Vascular disorders **Common:** • Hypotension	**Refer back to specialist services**
Respiratory, thoracic and mediastinal disorders **Common:** • Upper respiratory infection • Dyspnoea • Cough	**Refer back to specialist services**

Result	Action for primary care
Gastrointestinal disorders **Very common:** • Nausea • Vomiting **Common:** • Dyspepsia • Diarrhoea • Abdominal pain • Abdominal pain – upper • Constipation	**Refer back to specialist services**
Skin and subcutaneous tissue disorders **Common:** • Rash	**Refer back to specialist services**
Musculoskeletal and connective tissue disorders **Common:** • Myalgia • Muscle spasms • Back pain	**Refer back to specialist services**
General disorders and administration site conditions **Common:** • Asthenia	**Refer back to specialist services**

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

- Manufacturer advises patients and their carers should be counselled on the symptoms of hypocalcaemia and importance of serum-calcium monitoring.
- Manufacturer advises patients and carers should be counselled on the effects on driving and performance of skilled tasks due to increased risk of dizziness and seizures.

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

Pregnancy:

There are no clinical data from the use of cinacalcet in pregnant women. Animal studies do not indicate direct harmful effects with respect to pregnancy, parturition or postnatal development. No embryonal/foetal toxicities were seen in studies in pregnant rats and rabbits with the exception of decreased foetal body weights in rats at doses associated with maternal toxicities. Cinacalcet should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Breastfeeding:
It is not known whether cinacalcet is excreted in human milk. Cinacalcet is excreted in the milk of lactating rats with a high milk to plasma ratio. Following careful benefit/risk assessment, a decision should be made to discontinue either breast-feeding or treatment with Cinacalcet.

Paternal exposure*:*
There are no clinical data relating to the effect of cinacalcet on fertility. There were no effects on fertility in animal studies.

13. Specialist contact information

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Cambridge University Hospitals NHS Foundation Trust

CUH Endocrinology Department (primary hyperparathyroidism):

Specialist	Post	Telephone
Dr Victoria Stokes	Consultant Endocrinologist	01223 216218
Dr Lisa Yang	Consultant Endocrinologist	01223 216218

North West Anglia NHS Foundation Trust

NWAFT Endocrinology Department (primary hyperparathyroidism):

Specialist	Post	Telephone
Dr Singhan Krishnan	Consultant Endocrinologist	01480 416553
Dr Satyanarayana Sagi	Consultant Endocrinologist	01733 677501

NWAFT Nephrology Department (secondary hyperparathyroidism):

Specialist	Post	Telephone
Dr Frieder Kleeman	Consultant Nephrologist	01733 673699
Dr Bahareh Arsalanizadeh	Consultant Nephrologist	01733 673699
Dr Soubhik Pal	Consultant Nephrologist	01733 673699
Dr Khalid Abdelmagid	Consultant Nephrologist	01733 673699
Dr Hadeel Ahmed	Consultant Nephrologist	01733 673699
Dr Shaista Tamizuddin	Consultant Nephrologist	01733 673699
Dr Milton Das	Consultant Nephrologist	01733 673699
Dr Catherine Marshall	Consultant Nephrologist	01733 673699

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's primary care clinician or their contact details.

15. References

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- NICE. (n.d.). BNF is only available in the UK. [online]

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC).v
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care.
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care.
- NICE NG197: Shared decision making. Last updated June 2021.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

If there are any concerns in relation to the patient or their condition changes, primary care prescribers should contact the relevant initiating specialist using the **Specialist contact information** (see section 13).

Specialist teams should contact primary care prescribers via the usual communication routes agreed locally

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*: [insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]* NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.