

Request to Share Care and Agreement Form

**Cinacalcet for Use in Secondary Hyperparathyroidism in Adults with
End Stage Kidney Disease (ESKD) Requiring Renal Replacement Therapy:
Shared Care Protocol: Guideline No 1; Version 2**

This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 5 onwards).

GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 4.

For Completion by Specialist (with page 4 Shared Care Agreement Form)

Patient name.....

Addressograph label

DOB..... OR

NHS number.....

Dose:

Date of first prescription by specialist:

Estimated date for prescribing to be continued by the GP:

Next monitoring tests due and dates if not at 12 weekly monitoring:

Specialist additional comments/advice:

Key Primary Care Information (refer to Full Shared Care Protocol for further information)

GP RESPONSIBILITIES

- Consider request to shared care arrangements and prompt completion and emailed return of signed response to the Specialist using the Shared Care Agreement Form within 14 days of its receipt.
- If shared care accepted prescribe cinacalcet once patient is clinically stable in line with protocol. This is usually within 8-12weeks after initiation of therapy.
- Prescribe as per recommendation from specialist. Ensure ongoing monitoring undertaking by specialist.
- There should be reciprocal sharing of blood tests between the GP and specialist.
- Re-iterating with the patient that non-attendance for blood testing may lead to withdrawal of the medication. Further help and advice can be sought from the hospital specialist team.
- Appropriately prompt notification to the hospital Specialist of any significant and relevant changes in the patient's condition or of an adverse reaction, referring to Specialist should any serious side effects occur. Stop treatment on advice of the Specialist or immediately if an urgent need to stop treatment arises.
- Ensure no drug interactions with other medicines.
- Advise specialist of any change in the smoking status of the patient since this may require a dose change.
- Change dose or stop treatment as advised by Specialist.
- Inform the specialist team if severe side effects or potential overdose is apparent.
- Report adverse events to the Specialist and MHRA/CHM.

MONITORING AND ACTIONS TO BE TAKEN

Monitoring Table – see GP monitoring highlighted in grey

Monitoring table		Hospital specialist	Hospital specialist	GP	Hospital specialist
Test	Indication	Pre-treatment baseline	Following treatment initiation and ongoing	Ongoing	Annual review
Parathyroid Hormone (PTH)	To assess suitability for treatment, disease and drug monitoring. Dose to be titrated according to response to achieve target PTH (15.9-31.8pmol/L)	√	*Monthly monitoring at initiation or dose adjustment then every 3 months during maintenance	Not required by GP	√
Calcium and phosphate	Baseline and ongoing assessment for disease and drug monitoring	√	Measure within a week of initiation or dose adjustment then measure monthly	Not required by GP	√

Action to be taken if Abnormal Result

GP will be informed by specialist via letter.

(Normal reference range may vary slightly between labs. Results should be recorded in the patient's shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, Specialist will advise)

- The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing.
- Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
 - Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
 - Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
 - Specialist and patient have completed and signed the shared care agreement form (page 3).

Shared Care Agreement Form

This form is used to agree shared care between the Specialist, patient and GP.

Specialist and patient agreement

By signing below we accept:

- the Herts and West Essex Area Prescribing Committee shared care principles (HWE APC) and
- the requirements and responsibilities defined in this drug specific shared care protocol

Specialist name:	Patient name or addressograph label:
Designation:	<div style="border: 1px dashed black; width: 80%; margin: 0 auto; height: 80px;"></div>
Provider Trust:	
Direct telephone number:	
Email:	
Email (for use by GP to respond to request to share care):	Send to pharmacy when completed:- Via E-Mail: Sharedcare.enh-tr@nhs.net Via Post: Lister Pharmacy L83
Date:	Specialist Signature:
Date:	Patient Signature:

GP response to shared care

Please return to specialist **within two weeks** of receipt of request to share care.

This form is to be completed by the GP who is requested to share care.

I agree to accept shared care for this patient as set out in this shared care protocol and HWE APC shared care principles

I do not accept shared care for this patient

My reason(s) for not prescribing are given below:

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

GP name:	Practice address /stamp:
Direct telephone number:	
Email:	
Date:	
	GP Signature:

Please return a copy of the completed form to the requesting specialist **within two weeks** of receipt of request to share care (preferably by email). Sharedcare.enh-tr@nhs.net

1. Specialist to retain copy in patient's hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient's notes.

Full Shared Care Protocol

Cinacalcet for Use in Secondary Hyperparathyroidism in Adults with End Stage Kidney Disease (ESKD) Requiring Renal Replacement Therapy: Shared Care Protocol: Guideline No 1; Version 2

This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with HMMC shared care principles, [Summary of Product Characteristics \(SPC\)](#) and the [BNF](#).

BACKGROUND AND INDICATION(S) FOR USE

Secondary hyperparathyroidism occurs in patients with chronic kidney disease (CKD), where increasing serum phosphate and decreasing active vitamin D levels result in a reduction in serum calcium. Parathyroid hormone (PTH) production is increased to correct the low calcium level. Due to renal failure, vitamin D levels remain low and PTH levels continue to rise. PTH causes phosphate and calcium to be released from the bone. Over a prolonged period, this leads to renal osteodystrophy, bone pain and fracture, soft tissue and vascular calcification and cardiovascular complications. If the calcium x phosphate product (obtained by multiplying serum phosphate and calcium levels) and PTH are raised, this has been shown to be a poor prognostic marker.

Current treatment options for secondary hyperparathyroidism include:

- Dietary phosphate restriction
- Phosphate binders
- 1-alfacalcidol
- **Cinacalcet**
- Parathyroidectomy

Cinacalcet

Cinacalcet is approved for use in line with the recommendations from (NICE TA117): ‘Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy’ and is recommended for the treatment of refractory secondary hyperparathyroidism in patients with end-stage kidney disease (including those with calciphylaxis) only for those who have ‘very uncontrolled’ plasma levels of intact parathyroid hormone (defined as greater than 85 pmol/litre [800 pg/ml]) that are refractory to standard therapy, and a normal or high adjusted serum calcium level, and in whom surgical parathyroidectomy is contraindicated, in that the risks of surgery are considered to outweigh the benefits.

Response to treatment should be monitored regularly and treatment should be continued only if a reduction in the plasma levels of intact parathyroid hormone of 30% or more is seen within 4 months of treatment, including dose escalation as appropriate (NICE TA117).

DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT

Adult dosage and administration

The starting dose for all patients is 30mg once a day.

This will be titrated according to response every 4 weeks to achieve a target PTH of 15.9 – 31.8pmol/L. Maximum dose is 180mg once a day.

The dose should be taken with the evening meal. PTH assay should be assessed at least 12 hours after taking cinacalcet.

Preparations available: Cinacalcet 30mg, 60mg, 90mg tablets

SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT

- Diagnose and select appropriate patients for treatment in line with the recommendations from NICE TA 117 ‘Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.’
- Confirm with the GP that the patient fulfils criteria from NICE TA117 for initiation and ongoing treatment.
- Discuss the potential benefits and side effects of treatment with the patient.
- Undertake pre-treatment counselling and document discussion in patient’s records. Provide patient/carer with relevant (preferably written) information on use, side effects, need for monitoring of medication and precautions including that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist. (*cont. page 5/9*)

- Obtain agreement and consent to share care. Complete and sign Specialist and patient agreement section of Shared Care Agreement form. Document in patient's notes and transfer once patient stabilised.
- Request for GP confirmation of acceptance of shared care by secure emailing of request to share care, protocol and completed agreement form, allowing 2 weeks for response.
- Receipt and recording in patient records/notes that GP has / has not accepted shared care and ensuring appropriate action if not (specialist to continue to prescribe/monitor).
- Prescribe for initial stabilisation period, usually 8-12 weeks.
- Undertake baseline and ongoing tests as indicated in the monitoring table. Review results of safety monitoring and request additional tests as required.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- Monitor response and adverse effects to treatment and need to continue therapy. Notify the GP of any changes to dose or cessation of therapy.
- Advise the GP on when to adjust the dose or to stop treatment.
- Notify GP if patient does not attend clinic repeatedly and advise on action to take.
- Provide any other advice, information or support for the GP if required. Communicate any clinically important issues and action to be taken and ensure clear back-up arrangements exist for GPs to obtain advice and support.
- Report any adverse events to MHRA/CHM and the GP.
- Support any training arrangements to ensure that GPs have the skills to ensure safe practice.

GP RESPONSIBILITIES

Refer to page 1 and GP Considerations for Shared Care page 8.

PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP

- Confirm their agreement with the decision to move to a shared care model for their ongoing care and their understanding of the shared care agreement.
- Consent to share care and complete/sign Specialist and patient agreement section of Shared Care
- Take the cinacalcet as prescribed.
- Attending for blood monitoring and follow up hospital or GP appointments.
- Report to the Specialist or GP if they subsequently do not have a clear understanding of the treatment.
- Ensuring a list of all medications is brought to all GP surgery, outpatient and A&E consultations.
- Reporting any change in symptoms and adverse effects promptly to the clinician who is currently prescribing.
- Confirm that no new medicines are started (including over the counter preparations) unless this has been discussed with the GP, specialist or pharmacist.
- Share any concerns in relation to treatment with cinacalcet with the Specialist or GP.
- Inform Specialist, or GP, of any other medication being taken, including over-the-counter products.
- Alert GP/specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy, plans to move/change GP practice
- Inform Specialist and GP if there is a change in smoking status.

DISPENSING PHARMACIST RESPONSIBILITIES

- Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required. - Check the patient is being monitored regularly to ensure that it is safe before issuing or dispensing prescriptions.
- Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required

MONITORING AND ACTIONS TO BE TAKEN

- Refer to page 2.

SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO [BNF](#) AND [SPC](#) for full details)**Side effects:**

SIDE EFFECTS	Action to be taken by GP
Gastro-intestinal e.g. nausea, vomiting	Very Common - Monitor and inform specialist if symptoms become significant.
Hypocalcaemia	Common – This will be picked up by specialist reviewing the bloods
Seizures	*SPC states ‘common’ – Stop cinacalcet and inform specialist if new seizures or increase in frequency. <i>Renal local experts confirmed this has not been observed in a non-epileptic patient. Where a patient has a history of epilepsy or is on treatment as such, the renal team would not select cinacalcet for that reason. (local experience and feedback noted by Renal Team, East and North Herts)</i>

- GP to liaise with specialist if any side effects are a cause for concern.

CONTRAINDICATIONS AND PRECAUTIONS (REFER TO [BNF](#) AND [SPC](#) for full details)

Hypocalcaemia: Cinacalcet reduces parathyroid hormone which leads to a decrease in serum calcium concentrations.

Hypersensitivity to the active substance or any of the excipients: see the Summary of Product Characteristics (SPC) for further information.

Conditions that may worsen with a decrease in serum-calcium concentrations: Manufacturer advises caution with use in patients with conditions that may worsen with a decrease in serum-calcium concentrations, including predisposition to QT-interval prolongation, history of seizures, and history of impaired cardiac function.

Pregnancy and breastfeeding: Only use in pregnancy if benefit outweighs the risk.

NOTABLE DRUG INTERACTIONS (REFER TO [BNF](#) AND [SPC](#) for full details)**Common drug interactions**

Rifampicin: Cinacalcet levels may be reduced

Ritonavir: Cinacalcet levels may increase

Ketoconazole/Itraconazole: Cinacalcet levels may increase

Smoking: Cinacalcet levels may be reduced in patients who smoke. Dose may need adjusting if the patient starts or stops smoking.

Metoprolol/tricyclic antidepressants: Cinacalcet may possibly increase blood levels of these drugs (this is not an important interaction in the BNF).

CONTACT DETAILS for BACK-UP INFORMATION / ADVICE**East and North Hertfordshire NHS Trust**

Specialist and designation	Contact number	Specialist Team designated nhs.net email	Pharmacy Team shared care admin contact	Out of hours contact / switchboard
Consultant nephrologists	via switchboard	nephadmin.enh-tr@nhs.net	sharedcare.enh-tr@nhs.net 01438 284032	01438 314333
Clare Morlidge/ Charlotte Mallindine Renal pharmacists	01438 284677	renalpharmacists.enh-tr@nhs.net		
Renal dietician	01438 284947	renaldiicians.enh-tr@nhs.net		

Outside normal working hours there is access to a Consultant Nephrologist via the hospital switchboard

For any queries relating to a patient's treatment with cinacalcet, please contact the specialist as documented at the top of this document. Read in conjunction with HWE APC shared care principles document. For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call.

REFERENCES

- NICE technology appraisal guidance 117. Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. <http://guidance.nice.org.uk/TA117>
- BNF, No 81, March 2021. <https://bnf.nice.org.uk/>
- Summary of Product Characteristics for cinacalcet tablets, Tillomed Laboratories Ltd, August 2020 www.medicines.org.uk
- Hull and East Riding's NHS Trust Cinacalcet Shared Care Guidelines, Sept 2007

GP Considerations for Shared Care

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol. **The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
- Have you been provided with relevant clinical details including monitoring data?
- Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its use as well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient's condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

Approval Information

Title of Guideline	Cinacalcet for Use in Secondary Hyperparathyroidism in Adults with End Stage Kidney Disease (ESKD) Requiring Renal Replacement Therapy: Shared Care Protocol
Guideline Number	1
Version	2
Review Date	This shared care guidance will be reviewed upon request in the light of new evidence becoming available
Original Version Produced	NA
Approvals:	
Provider Trust Drug / Formulary Management Group	To be noted at East and North Hertfordshire NHS Trust Therapeutics Policy Committee
Hertfordshire and West Essex area prescribing committee	November 2023
Author/s	East and North Hertfordshire NHS Trust Pharmacy department and relevant specialisms supported by HWE ICB Pharmacy and Medicines Optimisation Teams
Department(s) responsible for updating the guideline	East and North Hertfordshire NHS Trust Pharmacy department and relevant specialisms supported by HWE ICB Pharmacy and Medicines Optimisation Teams