NHS Dorset

SHARED CARE PROTOCOL - FOR THE USE OF CINACALCET FOR COMPLEX PRIMARY HYPERPARATHYROIDISM IN ADULTS

As well as 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

- Assess the patient and provide diagnosis; ensure that this diagnosis is within the scope of this shared care protocol (section 2) and communicated to primary care
- Use a shared decision-making approach; discuss the benefits and the risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision.

  Obtain and document patient consent.

  Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations; arrange and review the results of any blood tests for the first 12 weeks of treatment (see section 8).
- Initiate, assess response and optimise treatment as outlined in section 5. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- Explain the intention to share care for drug prescribing and monitoring to the patient. Explain the process and the potential timescales for this.

  Once treatment is optimised, complete the shared care documentation either using the documentation in Appendix 1 or by clinic letter, detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information (section 13).
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.

- Conduct scheduled reviews and monitoring in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued, dose amended or stopped. Confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Ensure there is a mechanism to receive rapid referral of a patient from primary care in the event of deteriorating clinical condition, non-adherence to monitoring requirements or need for further advice and support.

  Provide advice to primary care on the management of adverse effects if required.
- Review treatment and reassume prescribing responsibilities if a patient becomes or wishes to become pregnant.
- Advise primary care if treatment should be discontinued.

Primary care responsibilities

- Respond to the request from the specialist for shared care **if further clarification or a refusal is intended. Acceptance of shared care is implied by nil response**. It is asked that this be undertaken within 14 days of the request being made, where possible
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5, taking into account potential drug interactions in section 7.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Manage adverse effects detailed in section 10 and discuss with specialist team when required.

  Discuss with the specialist if the patient plans to become pregnant.
- Treatment continuation decision (same, dose amended or stopped) as advised by the specialist. Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take medication as prescribed and avoid abrupt withdrawal unless advised by the prescriber.
- Maintain engagement with specialist and primary care. Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter (OTC) medications to their prescriber and be aware they should discuss any prescribed medication with their pharmacist before purchasing any OTC medicines.

- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist of GP immediately if they become pregnant or wish to become pregnant.

1. Background

Back to top

This shared care guideline has been prepared to support the transfer of responsibility for prescribing from secondary to primary care. Shared Care is only appropriate if it provides the optimum solution for the patient.

2. Indications

Back to top

This document only covers use of cinacalcet when used for complex primary hyperparathyroidism in adults. Cinacalcet is indicated for reducing hypercalcaemia in adult patients with primary hyperparathyroidism (PHPT) for whom parathyroidectomy would be indicated based on serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is **not clinically appropriate or is contraindicated.**

Primary hyperparathyroidism (PHPT) is a common illness that affects the parathyroid glands. In PHPT there may be higher than normal levels of parathyroid hormone (PTH) compared to the level of calcium in the body. This increases blood calcium levels. Both higher PTH and calcium causes the symptoms of PHPT.

Two of the most important long-term problems with PHPT are:

- Osteoporosis (loss of bone density) with increased risk of fractures
- Increased risk of kidney stones

PHPT has also been linked with many other common illnesses. Further guidance is available in the NHS England document.

Use of cinacalcet for other indications falls outside the remit of this guidance – in such cases refer to Dorset formulary.

3. Locally agreed off-label use

Back to top

N/A

4. Contraindications and cautions

Back to top

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:

Cinacalcet is contra-indicated in patients with:

- Hypersensitivity to the active substance or to any of the excipients listed in the summary of product characteristics.
- Hypocalcaemia
- Vitamin D deficiency

Cautions

- Patients with a history of a seizure disorder
- Hepatic insufficiency

Heart failure / prolonged QT interval

5. Initiation and ongoing dose regimen

Back to top

The specialist will prescribe at least the first three months of cinacalcet treatment and ensure the patient understands their treatment, including which side effects to report promptly and advise the patient to stop treatment if they experience hypotensive side effects.

Initial stabilisation: Initially 30mg twice daily (max per dose 90mg 4 times a day), dose to be adjusted every 2-4 weeks according to response.

Maintenance dose (following initial stabilisation): Usual maintenance dose is 30-60mg once or twice daily. Maximum licensed dose is 90mg orally four times daily.

Conditions requiring dose adjustment: See further information on prescribing in elderly and patients with hepatic impairment on BNF and SPC.

Stopping treatment: To be stopped if ineffective. Otherwise, usually lifelong as hypercalcaemia returns when stopped.

6. Pharmaceutical aspects

Back to top

Route of administration:	Oral
Formulation:	Tablet
Administration details:	For oral use, with or shortly after food. Tablets should not be chewed or crushed.
Other important information:	Cinacalcet is recommended to be taken with food or shortly after a meal – studies shown that bioavailability is increased when taken with food.

7. Significant medicine interactions

Back to top

*Please refer to the summary of product characteristics **SPC** and the BNF for a full list of potential drug interactions, the list below is not exhaustive.*

Primary care prescribers should carefully consider potential drug interactions when newly prescribing or stopping concurrent medication and carry out any necessary monitoring of the patient.

Medicines metabolised by CYP2D6	Cinacalcet is a strong inhibitor of CYP2D6. Dose adjustments may be required when cinacalcet is used with individually titrated, narrow therapeutic index substances predominantly metabolised by CYP2D6 (e.g. flecainide, propafenone, metoprolol, desipramine, nortriptyline, clomipramine).
CYP3A4 inhibitors/inducers	Cinacalcet is metabolised by CYP3A4 – caution is advised with potent inhibitors (e.g. ketoconazole) and inducers (rifampicin) of this enzyme.
CYP1A2 inhibitors/inducers	Caution with use of CYP1A2 inhibitors (e.g. ciprofloxacin). Smoking is a CYP1A2 inducer and may require dose adjustments if patient starts/stops smoking while on cinacalcet treatment.
Medicines known to lower serum calcium	Administer cinacalcet with caution. Closely monitor serum calcium.
Etelcalcetide	Patients on cinacalcet should not be given etelcalcetide. Concurrent administration may result in severe hypocalcaemia.

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

Back to top

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 monitoring / investigations	measure serum-calcium concentration before initiation of treatment.
Initial monitoring / investigations	Measure serum-calcium concentration within 1 month after starting treatment or adjusting dose.
Initial supply	Supply at least the **first three months** of treatment
Ongoing monitoring	Once treatment initiated and stabilised, measure serum-calcium concentration every 3 months.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

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

Monitoring – all indications	**Frequency**	**Action**
serum-calcium concentration	every 3 months	If corrected serum calcium levels fall below 8.4 mg/dL (2.1 mmol/L) and/or symptoms of hypocalcaemia occur contact specialist for advice.

(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

Back to top

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.

ADR frequency	Potential ADRs
Common (>1 in 10) **or very common** (between 1 in 10 and 1 in 100)	Reflux most common in practice Anorexia; asthenia; dizziness; myalgia; nausea; paraesthesia; rash; reduced testosterone concentrations; vomiting
Uncommon (between 1 in 100 and 1 in 1,000)	Diarrhoea; dyspepsia; seizures
Frequency not known	Allergic reactions; angioedema; heart failure; hypotension
ADR or Test result	**Action for primary care**
Worsening heart failure, QT prolongation, ventricular arrythmia secondary to hypocalcaemia	Stop cinacalcet and contact specialist for advice
Hypocalcaemia, hyperkalaemia, dizziness,	Stop or reduce dose and contact specialist for advice

paraesthesia, asthenia, headache	
Gastrointestinal, e.g. nausea, vomiting, decreased appetite, dyspepsia, diarrhoea, constipation, abdominal pain	Symptomatic management or trial reduced dose

11. Advice to patients and carers

Back to top

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

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

- Hypocalcaemia – signs of paraesthesia's, myalgias, cramping, tetany, prolonged QT, arrhythmias, convulsions
- Worsening liver function
- Seizures – potentially secondary to hypocalcaemia
- Hypersensitivity or rash

The patient should be advised to attend for 3 monthly blood tests.

12. Pregnancy, paternal exposure, and breast feeding

Back to top

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:

- Not recommended unless under specialist advice.

Breastfeeding:

- Not recommended unless under specialist advice.

13. Specialist contact information

Back to top

Please approach the patient's named secondary care clinician via the usual method of communication, currently email or letter.

14. Additional information

Back to top

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 of any changes to the patient's GP or their contact details. All involved healthcare professionals should ensure a prompt transfer of care that includes effective information sharing and continued access to the medicines by the patient during the transition.

15. References

Back to top

- Cinacalcet: Summary of Product Characteristics
- NHS England Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults
- BNF online, accessed 12/2024

16. Other relevant national guidance

Back to top

- Refer to page 10 of NHS England's guidance on Responsibility for prescribing between Primary & Secondary/Tertiary Care for more information/guidance about taking on prescribing of specialist medicines.

17. Local arrangements for referral

Back to top

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

Via the usual methods.

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 regarding 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.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) Not routinely used in the Dorset system, acceptance of shared care is implied by a nil return.

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patient's primary care prescriber, I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	

2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication, I am unable to take clinical responsibility for prescribing this medication at this time. Therefore, can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	

5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason, I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: _____

Date: _____

Primary Care Prescriber address/practice stamp