County Durham & Tees Valley
Area Prescribing Committee

Shared Care Protocol

Cinacalcet for patients within Endocrinology

This SCP is approved and adopted by the following subICBs and Trusts:

If not applicable to Trust or CCG state not applicable	County Durham	Tees Valley	North Yorkshire	County Durham & Darlington Foundation Trust	North Tees & Hartlepool Foundation Trust	South Tees Foundation Trust	Tees, Esk & Wear Valleys Foundation Trust
Date	12/01/23	12/01/23	07/12/22	12/01/23	12/01/23	12/01/23	*n/a*

1. Background	*Cinacalcet is a calcimimetic which inhibits PTH secretion by modulating the calcium sensing receptor of the parathyroid. This reduction in PTH levels leads to a reduction in serum calcium levels. It should be considered a second line therapy only. Cinacalcet is an effective treatment for symptomatic hypercalcaemia but it does not improve bone density in primary hyperparathyroidism.*
2. Indication(s) covered by this SCP **(Please state whether licensed or unlicensed)**	*Licensed indication for primary hyperparathyroidism when parathyroidectomy is not clinically appropriate, parathyroid carcinoma, parathyroid hyperplasia when parathyroidectomy is not clinically appropriate.*
3. Locally agreed off-label use	Nil
4. Contraindications and cautions Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	**Contraindications:** • Hypersensitivity to the active substance or to any of the excipients. • Hypocalcaemia **Cautions:** Please see SPC for comprehensive information.
5. Initiation and ongoing dose regime Note - •Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks •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 regimen :** 30mg twice daily **The titration period must be prescribed by the initiating specialist.** **Maintenance dose (following initial stabilisation):** Dose range from 30mg twice daily up to 90mg four times daily **The initial maintenance dose must be prescribed by the initiating specialist.** **Conditions requiring dose adjustment:** • Hepatic impairment use with caution as plasma levels of cinacalcet are elevated 2-4 fold. • Dose adjustments may be necessary if smoking started or stopped during treatment.

6. Pharmaceutical aspects	Route of administration:	Oral
	Formulation:	Tablets
	Administration details:	Will vary from bd to qds
	Other important information:	Swallow whole do not chew. Take with food to maximise absorption.

7. Significant medicine interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics. SPC

The following list is not exhaustive; please see SPC for comprehensive information and recommended management.

The following drugs must not be prescribed without consultation with the specialist:

- Etelcalcetide (may cause severe hypocalcaemia)
- Tamoxifen (May reduce metabolism of tamoxifen to active metabolite leading to breast cancer recurrence)

The following drugs may be prescribed with caution:

- See BNF/Stockleys for other interactions and monitoring requirements

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

Baseline investigations: Bone profile (serum calcium and phosphate), PTH, Urea, Electrolytes and Creatinine and LFT's.

Initial monitoring:

- 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 the GP.

Ongoing monitoring: Bone profile: weekly until dose stabilised (ensure hypocalcaemia does not ensue)

9. Ongoing monitoring requirements to be undertaken by primary care

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

Monitoring	Frequency
Serum Calcium, ensure no hypocalcaemia (requested as bone profile at South Tees Trust and include serum calcium plus phosphate)	3 monthly

10. Adverse effects and management

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

Result	Action for GP
Nausea and vomiting (often transient)	Symptomatic relief and if persistent refer back to specialist
Hypocalcaemia- calcium level <2.2mmol/L	Stop drug, contact specialist immediately
Seizures	Check serum calcium level and refer back to specialist
Prolongation of QT interval	Check serum calcium level and refer back to specialist
Hypotension and worsening heart failure	Check serum calcium level and refer back to specialist

11. Advice to patients and carers 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.	**The patient should be advised to report any of the following signs or symptoms to their GP without delay:** • Patients should be counselled on the symptoms of hypocalcaemia (paraesthesias, myalgias, cramping, tetany and convulsions.) and the importance of serum-calcium monitoring. • Increased risk of dizziness and seizures. Patient information on this medicine can be found at the following links:
12. Pregnancy, paternal exposure and breast feeding 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 GP and the specialist.	**Pregnancy:** There is no clinical data from the use of cinacalcet in pregnant woman. Cinacalcet should only be used in pregnancy if potential benefit justifies the potential risk to the foetus. **Breastfeeding:** It is not known whether cinacalcet is excreted in human milk. Following a careful risk/benefit assessment, a decision should be made to discontinue either breast-feeding or treatment with cinacalcet.
13. Specialist contact information	Name: *Simon Ashwell* Role and specialty: *Consultant Physician, Endocrinology* Daytime telephone number: *01642 835722* Email address: *simon.ashwell@nhs.net* Alternative contact: *On call Endocrinology Consultant, James Cook University Hospital* Out of hours contact details: *Via switchboard at James Cook University Hospital*
14. Additional information	Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.
15. References	• BNF • Mimpara SPC
16. To be read in conjunction with the following documents	• RMOC Shared Care Guidance • NHSE/NHSCC guidance – items which should not be routinely prescribed in primary care: guidance for CCGs • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
17. Local arrangements for seeking specialist advice Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.	**The following circumstances/ changes in the patient's condition require discussion with the specialist team:** • If pregnancy occurs or if the patient is planning to become pregnant or breastfeed. • If non-compliance is suspected or the patient fails to attend monitoring appointments and the primary care prescriber considers it no longer safe to continue prescribing. (All appropriate steps must first be taken by primary care to reinforce the importance of attendance to the patient) • The patient's clinical condition deteriorates such that the primary care prescriber feels a dose change is required/ the patient no longer appears to be benefiting from therapy
18. Version Control	Prepared by: Simon Ashwell (Consultant Physician, Endocrinology) & Emily Mogg (Rotational, General Medical Pharmacist) Checked by: Tracy Percival MO & Homecare Pharmacist Version: 1 Date of Issue / Review: 1/10/2021 Date for next Review: 1/10/2023 Approved by:

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 could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

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 patients 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: