



SHARED CARE Guideline – Amber Traffic Light Classification	
Name of medicine	Cinacalcet
Indication	Primary hyperparathyroidism for adults aged 18 years and above
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Organisation(s): Frimley Health Foundation Trust	
Date ratified by Frimley Health MOB (FH MOB):	22 nd September 2021

Frimley Health ICS Medicines Optimisation Board

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.

This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.

The SCG must be used in conjunction with the agreed core roles and responsibilities stated in annex A.

An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist

- Baseline monitoring and initial prescribing until the patient is established on treatment.
- Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review.
- Ensure that the patient has an adequate supply of medication until GP supply can be arranged.
- Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP.
- Patients will be reviewed in the endocrine clinic as per the Hospital Specialist's instructions
- Provide patients with advice about symptoms of hypocalcaemia e.g. paraesthesia, myalgia, cramping, tetany and convulsions.

General Practitioner's Responsibilities

- Ensure hospital is notified if unwilling to undertake prescribing and monitoring when requested
- Ensure monitoring is undertaken according to shared care guideline and only continue prescription if compliance with monitoring and results satisfactory.
- Follow guidance in the event of reaction or abnormality, record it and report back to the specialist
- To inform the endocrine team if patient repeatedly does not attend routine blood monitoring.
- Contact Hospital Specialist if treatment discontinued due to hypocalcaemia or if patient experiences any suspected related adverse drug reaction

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Patient Relatives & Carers

- Report symptoms of hypocalcaemia (paraesthesia, myalgia, cramping, tetany and convulsions) to GP or specialist urgently.
- Report any side effects of cinacalcet back to GP or specialist.
- Report changes in smoking status to GP or specialist. (see interactions below)
- Patients and careers should be counselled on the effects on driving and performance of skilled tasks—increased risk of dizziness and seizures.
- Take the prescribed dose of medication and attend scheduled appointments with GP and specialists.
- Attend recommended blood tests at the frequency outlined in this document.

Advice given regarding the Side effects

Provide patients with advice about symptoms of hypocalcaemia e.g. paraesthesia, myalgia, cramping, tetany and convulsions.

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at <https://bnf.nice.org.uk/> and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Cinacalcet is indicated for the treatment of hypercalcaemia in primary hyperparathyroidism for patient who are awaiting surgery or for those patients whom parathyroidectomy is not clinically appropriate, is contraindicated or for those patients who refuse surgery. Cinacalcet is a calcimimetic agent which directly lowers parathyroid hormone (PTH) levels by increasing the sensitivity of the calcium sensing receptor to extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

Duration of treatment will be prior to parathyroidectomy or for those not suitable for surgery then long term treatment will be required based on calcium levels.

Further information can be found at: <https://www.england.nhs.uk/wp-content/uploads/2017/06/ccp-cinacalcet-complex-primary-hyperparathyroidism-adults.pdf>

Indication

As per NICE guidelines [NG132] available at <https://www.nice.org.uk/guidance/NG132> cinacalcet may be considered if
1) if the albumin-adjusted serum calcium levels is more than 3 mmol/L without any symptoms of hypercalcaemia or
2) if albumin-adjusted serum calcium level is more than 2.85 with symptoms of hypercalcaemia and not suitable for surgery/ or pre surgery to bring the calcium down.

Dosage and Administration

Initial Regime:

In primary hyperparathyroidism, the starting dose is 30mg twice daily, adjusted in increments of 30mg twice daily every 2 - 4 weeks according to response up to a maximum of 90mg four times a day. Doses greater than 90mg twice daily should be split into three or four divided doses.

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Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Pre-treatment: <ul style="list-style-type: none"> Confirm the diagnosis of primary hyperparathyroidism with a decision to initiate cinacalcet. Baseline investigations: Bone profile, PTH, U&Es, LFTs, Vitamin D. Vitamin D – replacement as indicated. 	Hospital Endocrine consultant
Initiation: <ul style="list-style-type: none"> Indicated if the calcium more than 3 mmol/L without any symptoms of hypercalcaemia or more than 2.85 with symptoms of hypercalcaemia. Dose titration as per the SPC until adjusted calcium is between 2.50 and 2.70 mmol/L. Frequency of monitoring: Adjusted calcium 1 week after initiation or dose change. 	Hospital Endocrine consultant
Maintenance: <ul style="list-style-type: none"> Once adjusted calcium levels are in the desired range and stable then care and prescribing can be transferred to primary care prescriber. Frequency of monitoring and responsible clinician: <ul style="list-style-type: none"> Adjusted calcium every 3 months (aim between 2.50 – 2.70 mmol/L) – by primary care prescriber. Vitamin D (aim 50 - 100 nmol/L), U&Es and bone profile every 12 months – by hospital Endocrine Consultant. 	Primary care prescriber Annual review by hospital Endocrine Consultant for stable patients and more frequent reviews for unstable patients
If dose change when on maintenance: <ul style="list-style-type: none"> Adjusted calcium below 2.50 or above 2.70 mmol/L. 	Hospital Endocrine consultant

Abnormal results – Actions to be taken

Test	Abnormal Result	Action if Abnormal Result
Adjusted Calcium	< 1.90 mmol/L	Contact on call team – treat as medical emergency
Adjusted Calcium	Calcium between 1.90 and 2.20 mmol/L	Contact patient to stop cinacalcet. Refer to Endocrine consultant for dose review
Adjusted Calcium	Calcium between 2.20 - 2.50 mmol/L	Contact Endocrine consultant for potential dose reduction
Adjusted Calcium	Calcium between 2.50 – 2.70 mmol/L	Continue maintenance dose
Adjusted Calcium	Calcium between 2.70 – 3.20 mmol/L	Contact patient to assess symptoms. Depending of clinical scenario refer to hospital specialist for dose adjustment or contact on call team.
Adjusted Calcium	> 3.20 mmol/L	Contact on call team – treat as medical emergency

Cautions, contraindications: Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk
 Include only where no SPC is available, i.e. for unlicensed /off-label use, and in line with approved use as per FH formulary

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Adverse effects and action to be taken (if appropriate) - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Ensure patient is counselled about symptoms of hypocalcaemia. Clinical manifestations include paraesthesias, myalgias, cramping, tetany and convulsions.

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Concurrent administration of other medicinal products known to reduce serum calcium and cinacalcet may result in an increased risk of hypocalcaemia.

Cinacalcet is metabolised in part by enzymes CYP3A4 and CYP1A2. Strong inhibitors and inducers of these enzymes may result in increased or decreased cinacalcet levels respectively. Patients should be instructed to report changes in smoking status since this can induce metabolism of cinacalcet. If a patient starts or stops smoking then dose adjustment may be required.

Cinacalcet is a strong inhibitor of CYP2D6. Dose adjustments of medicinal products that are metabolised by this enzyme may require be required on following initiation, dose change or discontinuation of cinacalcet.

Support and Advice Contact Details for Primary Care Prescribers:

Consultants Name	Speciality	Email address
Dr Alireza Mohammadi Dr Binu Krishnan Dr David Dove Dr Hema Heffernan Dr Rajee Baburaj Dr Sriranganath Akavarapu Dr Zaw Htet	Endocrinology at WPH	Contact directly on Advice and Guidance. If known to a particular consultant please direct Advice and Guidance request directly to them. Endocrine secretary: fht.endocrinologysecretarywph@nhs.net or 0300 6153146
Dr Aye Naing Dr Frances Coyle Dr Isuri Kurera Dr Jennifer Tringham Dr Rasha Mukhtar Dr Shang Shaho	Endocrinology at FPH	Contact directly on Advice and Guidance If known to a particular consultant please direct Advice and Guidance request directly to them. Endocrine secretary: fht.endocrine.diabetessecretariesfph@nhs.net 0300 613 4009

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Annex A: Agreed core roles and responsibilities for the shared care of medicines

Patients

To get the most out of your treatment it's important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing.

- You must make sure that you understand about your treatment
- If you do not understand ask for more information from the person prescribing the medicine
- Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication
- You must raise any concerns about your treatment with the person prescribing the medicine
- Talk to the specialist and come to an agreement of how the treatment should be provided to you
- Give permission to have aspects of your care communicated to healthcare providers
- You must attend all appointments
- You must keep a written list of all of the medicines you are taking
- You must keep lists of any additional vitamins, minerals, or other dietary supplements
- You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital
- You must carry these lists on you in case of an emergency
- You must not let anyone else take your medication
- Report adverse effects.

It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit:

www.gov.uk/government/publications/the-nhs-constitution-for-england

Relatives and Carers

- To support the patient in fulfilling their roles and responsibilities as outlined above.

Consultant/ Specialist

Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required ^(Ref GMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign ^(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the Frimley Health Foundation Trust Area Prescribing Committee with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the Frimley Health Formulary.
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley Health Foundation Trust Area Prescribing Committee.

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.

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- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Post transfer of care

- Follow up and monitor the patient at appropriate intervals.
- Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
- Inform Primary Care Prescriber if patient does not attend planned follow-up

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the Frimley Heath Area Prescribing Committee as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements

Shared care agreement for: **Cinacalcet Primary hyperparathyroidism for adults aged 18 years and above**

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- Undertake all relevant monitoring as outlined in the monitoring requirements section above, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation's Frimley Health Foundation Trust Area Prescribing Committee representative who will facilitate an update at the Committee.

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