



SHARED CARE GUIDELINE

CINACALCET HYDROCHLORIDE:

Treatment of Primary Hyperparathyroidism in Adults

INTRODUCTION

Introduction and General statements	<ul style="list-style-type: none"> The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between consultant and primary care prescriber. The primary care prescriber will be provided with a copy of the shared care guideline or a link to where to find it on the South West Yorkshire Area Prescribing Committee's website. The primary care prescriber must reply in writing to the request for shared care within two weeks if <u>unwilling</u> to participate. The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and general practice notes. Shared care should only be considered when the patient's clinical condition is stable or predictable. It has been agreed at the SWYAPC that cinacalcet is suitable for prescribing in primary care after initiation and stabilisation by the hospital specialist. If a GP is uncertain about their competence to take responsibility for the patient's continuing care, they should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If the GP is still not satisfied, they should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
Indication for therapy	<p>For the reduction of hypercalcaemia in patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but in who parathyroidectomy is not clinically appropriate, or is contraindicated.</p> <p>Licensed indications Unlicensed indications</p>
Monitoring required	<ul style="list-style-type: none"> Baseline tests <ul style="list-style-type: none"> Calcium and bone profile Vitamin D U&Es Parathyroid hormone (PTH) Routine tests/Monitoring <ul style="list-style-type: none"> Calcium and bone profile U&Es Parathyroid hormone (PTH) 24 hour urine calcium Bone mineral density (DEXA) Ultra sound scan on the renal tract <p>Frequency of the routine tests/disease monitoring will be specified by the hospital specialist and individualised to the patient.</p> <p>The hospital specialist will perform ongoing biochemical assessment of response to therapy and communicate the test results to the GP. They will advise on any subsequent adjustments of dose.</p>



	<p>There may, however, be occasions when a patient has been put on therapy and monitored over a period time (particularly in a frail elderly patient, who might find visits to out-patients difficult) that they could be discharged to the care of the GP with a treatment plan, with the option of the GP re-referring should any problems occur. This treatment plan will include the monitoring and frequency of testing that is required for the patient plus actions to be taken in light of any abnormal results.</p> <p>Serum calcium will be measured within 1 week after initiation, or dose adjustment, of cinacalcet. Once maintenance dose levels have been established, serum calcium will be measured (at the hospital) every 2 to 3 months. After titration to the maximum dose of cinacalcet required, serum calcium will be periodically monitored; if clinically relevant reductions in serum calcium are not maintained, discontinuation of cinacalcet therapy would be considered.</p> <p>Management of abnormal test results: Any abnormal test results ordered by the specialist will be managed by secondary care. For any monitoring undertaken by the GP, if calcium level is greater than 3.0mmol/L on cinacalcet or the patient has significant ongoing symptoms of hypercalcaemia, GP should seek urgent specialist advice.</p> <p>The following is a summary of prescribing information only. Consult the latest edition of the BNF and Summary of Product Characteristics</p>
<p>Dosage and administration</p>	<ul style="list-style-type: none"> • The licensed recommended starting dose is 30mg twice a day. See clinic referral letter for recommended dose for particular patient. • A significant number of patients can be managed on 30 mg once daily. If it is tolerated and patient remains symptomatic, dose will be increased to 30mg twice daily. The dosage should be titrated every 2 to 4 weeks through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily, and 90 mg three or four times daily as necessary to reduce serum calcium concentration to or below the upper limit of normal. The maximum dose used in clinical trials was 90 mg four times daily. GP's will not be asked to titrate dose, this is for information only. • It is recommended that cinacalcet be taken with food or shortly after a meal, as studies have shown that bioavailability of cinacalcet is increased when taken with food • This drug requires ongoing monitoring which does include blood tests. <p>The following information has been added as it supports information in the BNF and SPC</p> <p>Adverse drug reactions:</p> <p>In the controlled studies conducted so far the most commonly reported undesirable effect was nausea and vomiting. This was mild to moderate in severity and transient in nature in the majority of patients. It generally didn't require cessation of treatment.</p>



INDIVIDUAL'S RESPONSIBILITIES

Hospital specialist's responsibilities	<ul style="list-style-type: none"> Ensure current diagnosis of condition and the treatment options have been discussed and understood by the patient and their carers where appropriate. Ensure that the ongoing treatment has been agreed with and by the patient and carer where appropriate. To assess the suitability of the patient for this treatment To discuss the benefits and side effects of treatment with the patient/carer and where applicable the need for long term monitoring Checking for allergies, interactions and contra-indications To perform baseline tests To initiate treatment in agreement with the patient Advising if medication should be prescribed by brand, for effectiveness and safety purposes To assess and monitor the patients response to treatment until stable before prescribing transferred to General Practitioner (GP) To ask the GP whether they are willing to take over the prescribing and monitoring responsibilities under this drug guidance To advise the GP on dose to be prescribed and any titration schedule if appropriate To advise GP what routine monitoring will be completed by the specialist and what monitoring the GP will be responsible for To forward results of monitoring to GP Outlining to the GP when therapy may be reduced and stopped assuming no relapse in patient's condition. Review periods to be agreed To ensure the patient is aware of the importance of not omitting doses, or stopping treatment other than on medical advice. Responding to issues raised by GP and informing the patient (and carers) of any material changes to any advice shared or agreements made at the outset To monitor the patient for adverse events and report to the GP and where appropriate Commission on Human Medicines/MHRA (Yellow card scheme) https://yellowcard.mhra.gov.uk/further-information/
Primary care prescribers responsibilities	<ul style="list-style-type: none"> Checking for allergies, interactions and contra-indications when taking over prescribing and when changing treatment To ensure all required monitoring is up to date before prescribing To prescribe cinacalcet and adjust the dose as recommended by the specialist following initiation and stabilisation by the specialist To discuss with/refer back to the specialist if the patient's condition deteriorates. Monitoring the patient's overall health and wellbeing, observing patient for evidence of ADRs and liaising with secondary care clinician if necessary. Routine disease monitoring should continue. Confirm, in line with the information already provided by the secondary care clinician, (or other clinician acting on their behalf) the circumstances under which the medicines should be immediately stopped and what action the patient is to take. Ensuring advice is sought from the responsible secondary care clinician if there is any significant change in the patient's physical health status that may affect prescribing or appropriateness of the medicine. Or any information relevant to their care that becomes available that was not made available at the time of the secondary care diagnosis and treatment option agreement Reducing/stopping treatment in line with secondary care clinician's



	<p>original request</p> <ul style="list-style-type: none"> • Take reasonable steps to ensure that the patient is using their medicines as prescribed and intended, i.e. include medication as part of medication review • To stop treatment on the advice of the specialist • Refer back to the specialist for review if the patient starts or stops smoking • To alert the endocrinologist to any identified non-compliance with cinacalcet. • Encourage the patient at medication review appointments to ask questions and raise any concerns they have about their treatment, particularly anything that may be affecting their adherence to treatment. Use the https://meandmy Medicines.org.uk • To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme) https://yellowcard.mhra.gov.uk/further-information/
<p>Information given to the patient</p>	<ul style="list-style-type: none"> • To be responsible for taking cinacalcet as prescribed • To ensure that there is an agreed process in place for accessing the ongoing supply of the medicines that is not placing any unnecessary burden or workload on the patient or their carers. The duration of treatment prescribed initially by the hospital specialist should be understood. • To attend for blood tests/disease monitoring on time (if appropriate) • To understand potential for adverse events and report these to the Specialist and/or GP. • To check with the community pharmacist that there are no interactions with cinacalcet, when buying any over the counter medicines or herbal/homeopathic products. • To inform the specialist and/or GP of any changes in smoking habits. • To check with dentists or other specialists who may prescribe medicines that there are no interactions with cinacalcet. • To contact the GP, Specialist or Medicines Information patient helpline if further information or advice is needed about this medication. More information on who and how to ask about medication can be found https://meandmy Medicines.org.uk
<p>Communication</p>	<p>Specialist to GP:</p> <ul style="list-style-type: none"> • The specialist will inform the GP when they have initiated cinacalcet and when there are any subsequent changes in treatment – standard clinic letter • Send a copy (either electronically or paper copy) of the Shared Care Guideline to the GP and ask whether they are willing to participate in shared care. • Inform the GP of the information provided to the patient. <p>GP to Specialist:</p> <ul style="list-style-type: none"> • To reply to the request for shared care within 2 weeks of receipt of the Consultant letter, if unwilling to participate. • Irrespective of whether you accept prescribing responsibility or not, you should inform the consultant of relevant medical information regarding the patient and changes to the patient's medication regime irrespective of indication. • Notify Consultant if treatment with cinacalcet is discontinued.
<p>Contact details</p>	<p>To be included in specialist's letter</p>

PRODUCT INFORMATION



The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics	
Serious adverse reactions	Refer to the current BNF and www.medicines.org.uk/emc/
Precautions and contra-indications	Refer to the current BNF and www.medicines.org.uk/emc/
Clinically relevant drug interactions and their management	Refer to the current BNF and www.medicines.org.uk/emc/
Pregnancy/breast-feeding:	Refer to the current BNF and www.medicines.org.uk/emc/