NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT

Shared care guidelines for use of Cinacalcet in patients with primary hyperparathyroidism where parathyroidectomy is contraindicated, refused by patient or not suitable as per NHSE Commissioning Policy 16034/P

Monitoring level - AMBER 2 - Prescribe the drug and perform a more intense level of monitoring, e.g. quarterly

Generic and Proprietary/Brand Name

Generic name - Cinacalcet 30mg, 60mg or 90mg film-coated tablets, **Brand name** - Mimpara®.

Please prescribe generically

Indications for shared care

For the treatment of primary hyperparathyroidism where parathyroidectomy is contraindicated, refused by patient or not suitable as per NHS England Cinacalcet commissioning guidance and where the patient's treatment plan is stable and can appropriately be managed jointly between primary and secondary care.

Specialist Prescribing and Monitoring Responsibilities – summary. Full details in main body of document	GP / Community Team - Primary Care Prescribing and Monitoring Responsibilities – summary. Full details in main body of document
• Assess the patient and establish the diagnosis, determine a treatment plan and ensure appropriate follow-up in conjunction with the GP • Initiate cinacalcet, monitor bloods (baseline and post-initiation) and stabilise treatment • Continue to monitor the patient and their therapy at three monthly intervals or, if patient stable, ask GP to do this • Provide the GP with appropriate prescribing and monitoring information • Provide advice if patient's condition changes • Ensure that procedures are in place for the rapid re-referral of the patient by the GP • Liaise with the GP on any suggested changes in prescribed therapy • Annual patient review for those transferred to GP for routine monitoring and prescribing • Ensure patient knows how to obtain medication supply and impact of smoking status changing • Report adverse effects to referring specialist and the MHRA yellow card scheme	• Initially, to refer the patient for specialist advice. • Where appropriate, to continue to prescribe cinacalcet as part of a shared care arrangement (usually after 4-8 weeks) as advised by specialist endocrinologist • Ensure no drug interactions with concomitant medications • Monitor serum calcium every 3 months, according to guidance from the specialist • Symptoms or results are appropriately actioned, recorded and communicated to secondary care where necessary • Seek cinacalcet monitoring advice if smoking status of patient changes • To report any adverse effects to the referring specialist and the MHRA yellow card scheme

Patient Information

- Patient must not exceed the recommended dose.
- Patients must attend their scheduled clinic and blood test appointments
- Report any adverse effects to the hospital specialist or GP
- Attempt to cease smoking and notify any change in smoking status to GP / specialist
- Share any concerns in relation to treatment with cinacalcet
- Patient should seek help urgently if suspect side effects, or otherwise unwell

Specialist Contact Details

Terri Carter – PA to Prof Jeremy Turner and link to Metabolic Calcium Service.
terri.carter@nnuh.nhs.uk OR terri.carter2@nhs.net 01603 287094

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.
- **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment
Primary hyperparathyroidism is a condition caused by over-activity of one or more of the four parathyroid glands and is a common endocrine condition. It is associated with increases in parathyroid hormone (PTH) levels and an increase in calcium and phosphate metabolism. Cinacalcet is indicated for reducing hypercalcaemia in adult patients with primary hyperparathyroidism (PHPT) for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated. Cinacalcet mimics the action of calcium on the parathyroid cells, suppressing PTH production. Further guidance is available in the NHS England guidance. A link can be found at the bottom of this document.
Licensed use and patient criteria
Treatment for patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels (as defined by relevant treatment guidelines), but in whom parathyroidectomy is not clinically appropriate or is contraindicated
Form and strength of preparation
Cinacalcet (Mimpara®) 30mg, 60mg or 90mg film-coated tablets – **please prescribe generically**
Side Effects and Management
Please see SPC for current guidance on side effects and adverse reaction
Drug Interactions
Please see SPC for current advice on drug interactions
Cautions and Contraindications
Please see SPC for current advice on contraindications Please see SPC for current advice on cautions for use
Initiation of therapy
Secondary Care Consultant Endocrinologist to initiate therapy via local specialist centre or multidisciplinary team
Initial dose, method of administration and supply
As per SPC, the recommended starting dose of Cinacalcet for **adults** is 30 mg twice per day. Dose 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. Serum calcium should be measured within 2 weeks after initiation or dose adjustment of cinacalcet. Once maintenance dose levels have been established, serum calcium should be measured every 3

months. After titration to the maximum/required dose of cinacalcet, serum calcium should be periodically monitored; if clinically relevant reductions in serum calcium are not maintained, discontinuation of cinacalcet therapy should be considered.

Cinacalcet is an oral medication that should be taken with or after food, preferably at the same time each day. Tablets should not be chewed or crushed.

Overdose of cinacalcet may lead to hypocalcaemia. In the event of overdose, patients should be monitored for signs and symptoms of hypocalcaemia, and treatment should be symptomatic and supportive. Since cinacalcet is highly protein-bound, haemodialysis is not an effective treatment for overdose

Hepatic impairment

No change in starting dose is necessary. Cinacalcet should be used with caution in patients with moderate to severe hepatic impairment and treatment should be closely monitored during dose titration and continued treatment

Maintenance dose

Maintenance dose will be determined by a patient's serum calcium concentration following titration

Duration of therapy / How the treatment will be reviewed and if appropriate, stopped

Long-term / specified by Endocrinologist

Baseline assessment and monitoring – by Specialist

Baseline biochemical monitoring will be undertaken by the specialist in addition to all ongoing routine blood monitoring as described below as part of the diagnosis and management of the condition (unless specifically agreed with the GP as per shared care agreement). This should include:

- Calcium before starting and within 2 weeks after initiation of drug
- Parathyroid hormone (PTH)
- Urea
- Electrolytes
- Creatinine
- Liver function tests (LFT)
- Phosphates

Serum calcium should be checked prior to initiation and monitored two to four weeks post initiation and following all dose adjustments by the hospital specialist. Once calcium is within the target range and patient is on a stable dose of cinacalcet, the hospital specialist can refer to GP for ongoing monitoring. GP should monitor serum calcium every three months.

Once stabilised on cinacalcet, acute derangements in calcium are rare with the exceptions of poor compliance with cinacalcet or clinical dehydration.

The GP should seek advice from the hospital specialist if calcium falls below 2.2mmol/L or rises above 2.6mmol/L

Specific consideration to compliance, interactions and smoking status should be made at initiation of therapy and throughout cinacalcet treatment in relation to serum calcium.

Specialist monitoring responsibilities

- Baseline biochemical monitoring prior to initiation
- Calcium should be monitored two to four weeks post initiation or following dose adjustment

GP / Community Team or other Primary Care monitoring responsibilities

- Once calcium is in the target range on a stable dose of cinacalcet, the GP should monitor calcium every 3 months

Consultant / Specialist prescribing responsibilities

- To assess the patient and establish the diagnosis, determine a treatment plan and ensure appropriate follow-up in conjunction with the GP
- To initiate cinacalcet, monitor bloods (baseline and post-initiation) and stabilise treatment
- To continue to monitor the patient and their therapy at three monthly intervals or, if patient stable, ask GP to do this. If GP accepts responsibility for routine monitoring and prescribing for patient, the specialist will still complete an annual review as part of the shared care agreement.
- To provide the GP with appropriate prescribing and monitoring information (letter dictation and 'outpatient GP recommendation' instruction on EPMA outpatient function, for rapid transfer of prescribing information)
- To provide advice if the patient's condition changes
- To ensure that procedures are in place for the rapid re-referral of the patient by the GP
- To liaise with the GP on any suggested changes in prescribed therapy in response to re-referral from GP
- Ensure patient knows how to obtain medication supply
- To report any adverse effects to the referring specialist and the MHRA yellow card scheme

GP prescribing responsibilities

- Initially, to refer the patient for specialist advice
- Review transfer of monitoring and prescribing responsibilities from secondary care for stable patients and respond with outcome accept/decline
- Where appropriate for patients whose transfer is accepted; continue to prescribe cinacalcet as part of a shared care arrangement (usually after 4-8 weeks) as advised by specialist endocrinologist
- Monitor serum calcium every 3 months, according to guidance from the specialist
- Symptoms or results are appropriately actioned, recorded and communicated to secondary care where necessary
- Ensure no drug interactions with concomitant medications
- Seek cinacalcet monitoring advice if smoking status of patient changes
- To report any adverse effects to the referring specialist and the MHRA yellow card scheme

Indications for referral back to Specialist

If calcium levels become abnormal during treatment the Endocrinologist should be notified in each case. If marginally out of range repeat test before action.

Monitoring	Frequency	Results	Action	By Whom
Calcium (Adjusted serum calcium)	3 monthly	2.2 – 2.6mmol/L	Review	GP
		<2.2mmol/L	Stop medication and refer to Endocrinologist	GP
		>2.6mmol/L	Refer to Endocrinologist for review	GP
Smoking Status		Smoking status changed	GP to notify Endocrinologist. Dose review may be required	GP

Further information and supporting documents

- Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults Reference: NHS England: 16034/P
- Cinacalcet SPC

Author(s) and Organisation	Prof Jeremy Turner (Consultant Endocrinologist) Jen Carroll TAG Lead Technician Samantha Sparrow DT&F Pharmacist
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1.1	Jan 2022	Jen Carroll, TAG Lead Technician, AGEM CSU	Draft	Updated following comments from Prof Jeremy Turner, Consultant Endocrinologist, NNUH
1.2	Feb 2022	Sam Sparrow DT&F Pharmacist, NNUH	Draft	Further updates – comments and track changes remain for info
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1.3	March 2022	As above	Final	Accepted by TAG and D+TC. Ratified by CCG Governing Body May 2022
2.0	Nov 2023	Jen Carroll, TAG Lead Technician, NWICB	Final	Request to prescribe generically, added to new template, formatting reviewed ready for transfer to new website