NHS
Lancashire and South Cumbria
Integrated Care Board

Lancashire & South Cumbria Medicines Management Group

Shared care protocol

Cinacalcet for the reduction of hypercalcaemia in adult patients with primary hyperparathyroidism for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but in whom parathyroidectomy is not clinically appropriate or is contraindicated

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Shared Care Protocol

Cinacalcet for patients within adult services

1. Background	This document applies to adults aged 18 and over. 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. Treatment with cinacalcet is recommended as an option by NICE (NICE guideline NG132)[1] if surgery has been unsuccessful, is unsuitable or has been declined for people with primary hyperparathyroidism and if their albumin-adjusted serum calcium level is either: • 2.85 mmol/litre or above with symptoms of hypercalcaemia **or** • 3.0 mmol/litre or above with or without symptoms of hypercalcaemia. Cinacalcet is a calcimimetic that increases the sensitivity of the calcium sensing receptor on the parathyroid to extracellular calcium, thereby inhibiting parathyroid hormone (PTH) secretion. The inhibition of PTH secretion then leads to a reduction in calcium levels. Once initial assessment and diagnosis have been undertaken, ongoing monitoring in people with asymptomatic primary hyperparathyroidism may be done in primary care. This includes patients who have been initiated and stabilised on cinacalcet, as generally their condition will be stable, similar to the average patient with primary hyperparathyroidism. Acute calcium derangements in these patients

	are rare, with the exceptions of poor compliance with cinacalcet or clinical dehydration.
2. Licensed and agreed off-label indications	Licensed indications: • Hypercalcaemia in parathyroid carcinoma. • Secondary hyperparathyroidism [in patients with end-stage renal disease on dialysis] • Primary hyperparathyroidism [in patients where parathyroidectomy is inappropriate]
3. Locally agreed indications for shared care	For the reduction of hypercalcaemia in adult 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.
4. Initiation and ongoing dose regime	**The loading period must be prescribed by the initiating specialist.** **The initial maintenance dose must be prescribed by the initiating specialist.** The recommended starting dose of Cinacalcet for adults is 30 mg twice per day.[3] The dose of cinacalcet 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. Once maintenance dose levels have been established, serum calcium should be measured every 3 to 4 months. After titration to the maximum 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
5. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist[4.5.6.7.8.9.10]	Monitoring at baseline and during initiation is the responsibility of the specialist, however the GP may be asked to assist with blood tests and prescribing for certain patients where attending hospital is problematic. Once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care. **Baseline investigations** • Serum-calcium concentration before initiation of treatment • Vitamin D. Vitamin D deficiency should be corrected before starting cinacalcet. • Parathyroid hormone (PTH) (for diagnosis but not for ongoing monitoring) • Bone profile • Urea and electrolytes **Initial monitoring** Dose adjustments every 2 to 4 weeks as per the specialist following calcium level monitoring. **Ongoing monitoring** Once calcium is in the target range on a stable dose of cinacalcet, the GP should monitor calcium every 4 months for a year from commencing cinacalcet and if adjusted calcium levels are well controlled patient then to be monitored / checked every 6 months. This is based on evidence that after 6 months

	adjusted calcium levels should not be significantly changing (Luque-Fernandez 2013).[11] PTH is not needed for ongoing monitoring.

6. Ongoing monitoring requirements to be undertaken by primary care

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.

Monitoring	Frequency
Serum Calcium	4 monthly for 12 months and then 6 monthly if well controlled

- The aim of treatment is to maintain adjusted calcium at between 2.40 and 2.85 mmol/L.
- The GP should seek advice from the hospital specialist if calcium falls <2.40mmol/L or rises >2.85mmol/L, as per the table below. Specialist advice should be sought either directly through the patient's named consultant via their secretary or through Advice & Guidance (A&G).
- Intercurrent illness—particularly dehydration or reduced oral intake—should prompt earlier calcium testing, as this can precipitate hypocalcaemia

Serum Adjusted Calcium	Action for GP
<2.20 mmol/L	Stop cinacalcet and seek immediate specialist opinion
2.20-2.39 mmol/L	Stop or reduce dose of cinacalcet and request advice from endocrinologist
2.40-2.85 mmol/L	Dose adequate. Maintain current dose. Ideal adjusted calcium 2.40–2.70 mmol/L; values up to 2.85 mmol/L remain acceptable
>2.85 mmol/L	Consider dose increase and/or request advice from endocrinologist. Repeat serum calcium after 2 weeks.

7. Pharmaceutical aspects

Route of administration:	Oral
Formulation:	Film coated tablets 30mg, 60mg, 90mg
Administration details:	Tablets should be taken whole and should not be chewed, crushed or divided. Cinacalcet should be taken with food or shortly after a meal.

8. Cautions and contraindications	This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF[12] & SPC for comprehensive information. • Cinacalcet treatment should not be initiated in patients with a serum calcium (corrected for albumin) below the lower limit of the normal range • Serum calcium levels should be closely monitored in patients receiving cinacalcet, particularly in patients with a history of a seizure disorder • Cases of hypotension and/or worsening heart failure have been reported in patients with impaired cardiac function

	• Administer cinacalcet with caution in patients receiving any other medicinal products known to lower serum calcium. Closely monitor serum calcium • In patients with moderate to severe hepatic impairment (Child-Pugh classification), cinacalcet should be used with caution in these patients and treatment should be closely monitored
9. Significant drug interactions	The following list is not exhaustive. Please see BNF & SPC for comprehensive information and recommended management. Concurrent administration of other medicinal products known to reduce serum calcium and cinacalcet may result in an increased risk of hypocalcaemia. Patients receiving cinacalcet should not be given etelcalcetide Concurrent administration of other medicinal products known to reduce serum calcium may result in an increased risk of hypocalcaemia. Cinacalcet is metabolised in part through cytochrome P450 enzymes CYP3A4 and CYP1A2 • Smoking induces CYP1A2 and therefore dose adjustments may be required if the patient starts or stops smoking during cinacalcet treatment. • Dose adjustment may be required if a patient receiving cinacalcet initiates or discontinues therapy with a strong inhibitor (e.g. azoles, telithromycin, ritanovir) or inducer (e.g. rifampicin) of CYP3A4.

10. Adverse effects and management

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance**.** For information on incidence of ADRs see relevant SPCs

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

Adverse effect	**Management**
Worsening heart failure, QT prolongation and ventricular arrhythmia secondary to hypocalcaemia	Stop cinacalcet and contact specialist for advice
Hypocalcaemia - hypocalcaemia in older adults can sometimes present subtly—such as irritability or cognitive slowing Hyperkalaemia Dizziness Paraesthesia Asthenia Headache	Stop or reduce dose and contact specialist for advice
Gastrointestinal e.g. Nausea, vomiting, decreased appetite, dyspepsia Diarrhoea Abdominal pain Constipation	Symptomatic management, or trial reduced dosage

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 drugs. **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 4 monthly blood tests.
12. Pregnancy, paternal exposure and breastfeeding	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. Document contraception advice at initiation and at each dose change. Consider pregnancy assessment in women of reproductive age at baseline and during titration. **Pregnancy**: There are no clinical data from the use of cinacalcet in pregnant women. Cinacalcet should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Not recommended unless under specialist advice. **Breastfeeding**: It is not known whether cinacalcet is excreted in human milk. Following careful benefit/risk assessment, a decision should be made to discontinue either breast- feeding or treatment with Cinacalcet. Not recommended unless under specialist advice.
13. Specialist contact information and arrangements for referral	The specialist team should: • initiate and titrate cinacalcet until patient is **stabilised** on the optimal dose for at least eight weeks. • ensure two consecutive adjusted calcium levels should be within the target range • ensure Vitamin D is replenished before transfer • make contact with the patient's GP requesting them to prescribe under a shared care agreement as soon as practicably possibly after the initial maintenance supply has been provided to the patient. The specialist may ask the GP to assist with arranging blood tests and initial supply of cinacalcet for patients unable to attend hospital. It will be the secondary care specialist that will remain responsible for reviewing results and dose titration of cinacalcet. • Share the results of any blood monitoring with primary care. • Reassess the patient after 4 months for clinical response. Before entering into a shared-care agreement, secondary care will advise the GP on frequency of monitoring, management of any dose adjustments and when to stop treatment. A short treatment summary should be provided containing the following: • The current cinacalcet dose • The two most recent adjusted calcium levels • The agreed monitoring plan • The target calcium range

	Secondary care should ensure that clear backup arrangements exist for GPs to obtain advice if required.
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. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.
15. References	1. NICE NG132 Hyperparathyroidism (primary): diagnosis, assessment and initial management. Recommendations | Hyperparathyroidism (primary): diagnosis, assessment and initial management | Guidance | NICE 2. NICE TA117 Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. Overview | Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy | Guidance | NICE 3. SPC Cinacalcet Search Results - (emc) 4. North Central London JFC Shared Care Guideline Cinacalcet Treatment of Primary Hyperparathyroidism SCG_Cinacalcet 5. Derbyshire (JAPC) Guideline on prescribing and monitoring of Cinacalcet for Primary Hyperparathyroidism Cinacalcet_guidance_on_prescribing_and_monitoring.pdf 6. Sheffield Area Prescribing Group Shared Care Protocol For Cinacalcet for Primary Hyperparathyroidism in Adults Cinacalcet_SCP.pdf 7. NHS Dorset shared care protocol -for the use of cinacalcet for complex primary hyperparathyroidism in adults Cinacalcet-Shared-Care-Protocol.pdf 8. Bedfordshire, Luton, and Milton Keynes shared care guideline - Cinacalcet for the management of primary hyperparathyroidism in patients with severe hypercalcaemia awaiting surgery or deemed unfit for surgical management cinacalcet-shared-care-Final-version-agreed-with-AG-june-22-1.pdf 9. Yorkshire Shared Care Guideline – Cinacalcet in primary hyperparathyroidism (Adults) Cinacalcet Shared Care Guideline December 2020.pdf 10. GMMMG Shared Care Guideline – for cinacalcet for primary hyperparathyroidism in adults GMMMG-SCP-Cinacalcet-primary-hyperparathyroidism-Adults-approved-June-2017-v2.1.doc 11. Experience with cinacalcet in primary hyperparathyroidism: results after 1 year of treatment. Luque- Fernandez I et al. Ther Adv Endocrinol Metab . 2013 Jun;4(3):77-81Experience with cinacalcet in primary hyperparathyroidism: results after 1 year of treatment - PubMed 12. BNF cinacalcet | Search results | BNF | NICE
13. To be read in conjunction with the following documents	• NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ • General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care • NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.