Bath and North East Somerset, Swindon and Wiltshire Together

SHARED CARE AGREEMENT

Cinacalcet for complex primary hyperparathyroidism in adults

Amber TLS – 1-3 months

Principles of Shared Care

Shared care agreements provide a framework for the seamless transfer of care from a hospital or specialist service setting to general practice, where this is appropriate and in the patient's best interest. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP (or other primary care prescriber) concerned and the patient to share their care.

Patients and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines.

The existence of a shared care agreement does not necessarily mean that the GP has to agree to and accept clinical and legal responsibility for prescribing; they should only do so if they feel clinically confident in managing that condition. Clinical responsibility for prescribing is held by the person signing the prescription, who must also ensure adequate monitoring.

Responsibilities of Secondary Care Specialist

- Initiate treatment and prescribe for the length of time agreed (which will be at least 1 month and usually up to 3 months) – this should be enough time to allow optimisation of treatment and demonstrate that the patient's response is consistent.
- Discuss the benefits and side effects of treatment with the patient.
- Review concurrent medications for potential interactions prior to initiation.
- Undertake the clinical assessment and relevant monitoring at baseline and during the initiation period.
- Communicate details of treatment to GP (in writing or via secure email) within the first month of treatment and ask the GP whether he or she is willing to participate in shared care.
- Discuss shared care arrangements with the patient/carer, obtain their consent and explain their responsibilities.
- Review the patient's condition, monitor response to treatment where indicated and advise monitoring details.
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring.
- Supply GP with clinic letter or discharge summary within 14 days of an outpatient review or inpatient admission, and inform GP if patient does not attend scheduled clinic appointments.
- Ensure that clear arrangements exist for GPs to obtain advice and support.
- Report adverse events to the MHRA.
- Stop treatment where appropriate or provide GP with advice on when to stop.

Responsibilities of Community Hospital Prescriber

- Prescribe cinacalcet at the dose recommended after the initiation period.
- Liaise with ward clinical pharmacist to obtain medicine supply for administration on the ward
- Undertake ongoing clinical assessment and relevant monitoring and following the initiation period.
- Review new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Report adverse events to the specialist and MHRA.
- Stop treatment on the advice of the specialist.
- Communicate discharge to specialist (in writing or via secure email), to enable arrangements for ongoing treatment.
- Provide 14 days treatment on discharge
- Supply GP with discharge summary, highlighting shared care status of medication and specialist involvement.

Responsibilities of GP/Primary Care Prescriber

- Reply to the request for shared care as soon as practicable using the forms linked here (in writing or via secure email).

- Prescribe cinacalcet at the dose recommended after the initiation period.
- Undertake ongoing clinical assessment and relevant monitoring following initiation period.
- Review any new concurrent medications for potential interactions.
- Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
- Report adverse events to the specialist and MHRA.
- Stop treatment on the advice of the specialist.

Responsibilities of Patient/Carer

- Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- Share any concerns in relation to treatment with cinacalcet.
- Report any adverse effects to the specialist or GP whilst taking cinacalcet.
- Attend appointments for clinical review and monitoring.

1. Summary of condition and treatment aims Include links to relevant clinical guidelines e.g. NICE	The aim of treatment with cinacalcet is to reduce the albumin-adjusted serum calcium "adjusted calcium" level and parathyroid hormone (PTH) level to reduce/alleviate the symptoms of primary hyperparathyroidism. Cinacalcet is a calcimimetic. It increases the sensitivity of the calcium sensing receptor on the parathyroid to extracellular calcium, thereby inhibiting PTH secretion. The inhibition of PTH secretion then leads to a reduction in calcium levels. This treatment is suitable for shared care due to it being licensed for complex primary hyperparathyroidism and its inclusion in NICE Guideline 132 Overview | Hyperparathyroidism (primary): diagnosis, assessment and initial management | Guidance | NICE	
2. Details of medicine and indication Please state whether licensed or unlicensed (off-label) use. Note that shared care is generally unsuitable for off-label prescribing unless it is a widely recognised use (e.g. included in BNF)	This medication is indicated for the treatment of: • Complex primary hyperparathyroidism in adults if surgery has been unsuccessful, is unsuitable or has been declined, and if their albumin-adjusted serum calcium level is either: 2.85mmol/litre or above with symptoms of hypercalcaemia or 3.0mmol/litre or above with or without symptoms of hypercalcaemia (NICE NG132 2019). • People whose initial albumin-adjusted serum calcium is 2.85mmol/litre or above with symptoms of hypercalcaemia, base decision on whether to continue treatment with cinacalcet on how well it reduced symptoms (NICE NG132 2019). • People whose initial albumin-adjusted serum calcium level is 3.0mmol/litre or above, based decisions on whether to continue treatment with cinacalcet on how well it reduced either symptoms or albumin-adjusted serum calcium level (NICE NG132 2019).	
3. Pharmaceutical aspects	Route of administration:	Oral
	Formulation:	Tablet
	Administration details:	Tablets should be swallowed whole, and not chewed or crushed.
	Other important information:	Cinacalcet should be taken with food or shortly after a meal. Studies show that bioavailability of cinacalcet is increased when taken with food.

4. Usual dose and frequency (including details of dose adjustments, e.g. in renal impairment) and duration of therapy Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results. 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.	The initiation dose will be determined by the specialist. The Summary of Product Characteristics recommends a starting dose for adults is 30 mg twice per day. The 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. If clinically relevant reductions in adjusted calcium are not maintained, discontinuation of cinacalcet therapy should be considered by the specialist. If patient responds well, treatment can be continued on an ongoing basis, based on adjusted calcium levels.
5. Baseline investigations and initial monitoring to be undertaken by specialist	**Baseline investigations** • Parathyroid hormone • Adjusted calcium • Liver Function Tests (Manufacturer advises caution in moderate to severe hepatic impairment). **Monitoring and frequency** • Adjusted calcium should be measured within 1 -2 weeks after initiation or dose adjustment of cinacalcet.
6. Ongoing monitoring requirements to be undertaken by primary care	**Monitoring and Frequency** • **Adjusted calcium level** – 3 monthly or as advised by specialist • **Efficacy** - Opportunistically at each review or following any reports of treatment failure/recurrence of symptoms. • **Adverse effects as per section 10 and BNF/SPC** - Opportunistically at each review or following any reports of adverse effects or intolerance associated with treatment.
7. Action(s) to be taken by primary care if abnormal result(s) **Use Cinapsis App to consult Specialist**	• If loss of efficacy occurs refer to specialist to consider dose increase. • If adverse effects, refer to specialist to consider suitability of ongoing treatment. • If calcium between 2.0 and 2.2, advise patient to stop cinacalcet for 2 weeks, repeat calcium in 2 weeks and consult Specialist • If calcium <2, contact the Specialist urgently to discuss • If calcium > 2.85mmol/L OR symptoms of hypercalcaemia at any level above normal, consult Specialist.
8. Cautions and contraindications Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	**Cautions [continued overleaf]** • **Serum calcium:** Life threatening events and fatal outcomes have been reported with hypocalcaemia in patients treated with cinacalcet. Manifestations of hypocalcaemia include: paraesthesias, myalgias, cramping, tetany and convulsions. Hypocalcaemia can also prolong the QT interval, potentially resulting in ventricular arrhythmia secondary to hypocalcaemia. • QT prolongation and ventricular arrhythmia have been reported in patients treated with cinacalcet. Use caution in patients with other risk factors for QT prolongation, e.g. congenital long QT syndrome or patients receiving medicinal products known to cause QT prolongation. • Cases of seizures have been reported in patients treated with cinacalcet. The threshold for seizures is lowered by significant reductions in serum calcium levels; therefore, serum calcium levels should be closely monitored, particularly in patients with a history of seizure disorder.

	• Cases of hypotension and/or worsening heart failure have been reported in patients with impaired cardiac function treated with cinacalcet, in which a causal relationship to cinacalcet could not be completely excluded and may be mediated by reductions in serum calcium levels. • Use cinacalcet with caution in patients receiving other medicines known to lower serum calcium. Closely monitor serum calcium. • Patients receiving cinacalcet should not be given etelcalcetide. Concurrent administration may result in severe hypocalcaemia. • Due to the potential for 2 to 4 fold higher plasma levels of cinacalcet 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. **Contraindications** • Hypersensitivity to the active substance or excipients (check SMPC Search Results - (emc) (medicines.org.uk) • Hypocalcaemia • Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.
9. Significant medicine and food interactions and management **For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)**	• Concurrent administration of cinacalcet and other **medicines known to reduce serum calcium** may result in an increased risk of hypocalcaemia. • Cinacalcet is metabolised in part by the enzyme CYP3A4. Dose adjustment of cinacalcet may be required in patients receiving therapy with a strong inhibitor (e.g. **ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir**) or inducer (e.g. **rifampicin**) of this enzyme. • *In vitro* data indicates that cinacalcet is part metabolised by CYP1A2. Smoking induces CYP1A2 and the clearance of cinacalcet was observed to be 36-38% higher in smokers than non-smokers. Dose adjustment may be necessary if a patient **starts or stops smoking** or when concomitant treatment with strong CYP1A2 inhibitors (e.g. **fluxoxamine, ciprofloxacin)** is initiated or discontinued. • Cinacalcet is a strong inhibitor of the enzyme CYP2D6. Dose adjustments of medicines products metabolised by CYP2D6 may be required (e.g. **flecainide, propafenone, metoprolol, desipramine, amitriptyline, notriptyline, clomipramine, imipramine, atomoxetine, dextromethorphan**). • Cinacalcet may increase exposure to **dosulepin, doxepin** and **lofepramine**, the manufacturer advises to monitor for toxicity and adjust the dose if necessary. • The BNF advises avoiding concomitant use with **tamoxifen**.

10. Adverse effects and management Include details of incidence, identification, importance and management. **For a comprehensive list, consult the BNF or Summary of Product Characteristics (SPC)**	**Adverse Effect**	**Action to be taken if detected**
	• GI disturbance: (esp. nausea and vomiting; usually transient.) • After taking cinacalcet a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension). • Unusually fast or pounding heart beat which may be associated with hypocalcaemia (QT prolongation and ventricular arrhythmia secondary to hypocalcaemia).	• If patient has hypocalcaemia, advise patient to stop taking cinacalcet and refer back to hospital to consider appropriateness of ongoing treatment. • Discuss other adverse effects with specialist • Serious suspected reactions, even if well recognised or causal link uncertain, should be reported to MHRA www.mhra.gov.uk/yellowcard

11. Advice to patients and carers The specialist will counsel the patient with regard to the benefits	• Report numbness or tingling around the mouth, muscle aches or cramps and seizures. These may be signs of hypocalcaemia. • Swallow cinacalcet whole with plenty of water, with or after food.

and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.	• Advise your GP or specialist if you are starting or stopping smoking, as this can alter the levels of cinacalcet and dose adjustment may be necessary. See section 9.
12. Pregnancy 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.	• There are no clinical data from the use of cinacalcet in pregnant women. Cinacalcet should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus. • It is not known whether cinacalcet is excreted in human milk. The manufacturer recommends that, following careful benefit/risk assessment, a decision should be made to discontinue either breastfeeding or treatment with cinacalcet. • There are no clinical data relating to the effect of cinacalcet on fertility. There were no effects on fertility in animal studies.
13. Specialist contact information	
	GWH — Via Cinapsis
	RUH — Via Cinapsis
	SFT — Via Cinapsis
	Other Specialist Contact Information
	• Click or tap here to enter text.
14. Additional information For example, process for when Specialist or GP changes roles; specific issues related to patient age/ capacity/ specific monitoring.	March 25: Please note that the 90mg cinacalcet tablets are significantly more expensive than the 30mg & 60mg tablets and are not available as a generic product. Local specialists will advise on patients' regimens that can be used to avoid the 90mg tablets.
15. References	• Summary of Product Characteristics for cinacalcet via https://www.medicines.org.uk/emc/search?q=cinacalcet • BNF online via https://bnf.nice.org.uk/drugs/cinacalcet/ • NICE Clinical Guideline for Hyperparathyroidism (primary): diagnosis, assessment and initial management. Published May 2019 via https://www.nice.org.uk/guidance/ng132
16. To be read in conjunction with the following documents	• NHS England: Responsibility for Prescribing Between Primary & Secondary/ Tertiary Care. Ref 07573, Version 1.0, Published January 2018. Accessed via: https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/

Written by (Author Name, Organisation & Role):	BSW ICB Formulary Pharmacists bswicb.formulary@nhs.net
Contributors:	Consultant Endocrinologists: Dr Vladimir Vaks GWH, Alex Ward & Chloe Broughton RUH, James Lawrence SFT
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Shared Care Response Templates:
Shared Care Agreements - Medicines