Healthier Together
Improving health and care in Bristol, North Somerset and South Gloucestershire

BNSSG Shared Care Guidance

Please complete all sections

Section 1: Heading

Drug	Cinacalcet
Amber *three months*	
Indication	Induction via specialist in line with NHS England policy Reduction of hypercalcaemia in adult patients with **complex 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. Consider cinacalcet •serum calcium 2.85 mmol/litre or above with symptoms of hypercalcaemia or •serum calcium 3.0 mmol/litre or above with or without symptoms of hypercalcaemia.

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	*Adults and elderly (> 65 years)* The recommended starting dose of Cinacalcet for adults is 30 mg twice per day. 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. The maximum dose used in clinical trials was 90 mg four times daily. Note: this is a licensed indication, dose & frequency. *Paediatric population* The safety and efficacy of cinacalcet in children for the treatment of parathyroid carcinoma and primary hyperparathyroidism have not been established. No data are available.
Route and formulation	Oral 30, 60 & 90mg film coated tablets
Duration of treatment	If clinically relevant reductions in serum calcium are not maintained, discontinuation of cinacalcet therapy should be considered. If patient responds well to treatment it can be continued on an ongoing basis, based on calcium levels.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Serum calcium should be measured within 1 week after initiation or dose adjustment of cinacalcet. Once maintenance dose levels have been established, serum calcium should be measured every 2 to 3 months. After titration to the maximum dose of cinacalcet, serum calcium should be periodically monitored.

Parathyroid hormone
Corrected serum calcium
Liver Function Tests
Renal function

Subsequent tests - where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
Serum calcium	Every 2-3 months (3 months min. standard interval requirement)	Primary care once stabilised	If calcium goes above normal range refer back to secondary care for dose adjustment, or stopping

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management

Side effect	Frequency/severity	Action/management
Nausea & vomiting	Very common	Refer back to secondary care for dose adjustment, or stopping.
Hypersensitivity reactions	Common	Stop cinacalcet. Discuss with endocrinology.
Anorexia & decreased appetite	Common	Refer back to secondary care for dose adjustment, or stopping.
Seizures, dizziness, paraesthesia & headache	Common	**Check calcium levels to exclude hypocalcaemia.** If present, stop cinacalcet. Refer back to secondary

		care for dose adjustment and review.
Myalgia, muscle spasms & back pain	Common	Refer back to secondary care for dose adjustment, or stopping.
Upper respiratory infection, dyspnoea & cough	Common	Discuss with endocrinology
Worsening heart failure & QT prolongation and ventricular arrhythmia secondary to hypocalcaemia	Frequency unknown	**Check calcium levels to exclude hypocalcaemia.** If present, stop cinacalcet. Refer back to secondary care for dose adjustment, or stopping.

Referral back to specialist	See above

Section 5: Other Issues
(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)
Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	*Drug Interactions* Cinacalcet has many drug interactions; if a new medication is started or a medication is stopped then the SPC & BNF should be consulted. 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 the enzyme CYP3A4.. Dose adjustment of cinacalcet may be required if a patient receiving cinacalcet initiates or discontinues therapy with a strong inhibitor or inducer of this enzyme. Cinacalcet is in part metabolised by CYP1A2. The effect of CYP1A2 inhibitors on cinacalcet plasma levels has not been studied. Dose adjustment may be necessary when concomitant treatment with strong CYP1A2 inhibitors is initiated or discontinued. *Contra-Indications* Hypocalcaemia *Cautions* ***Conditions that may worsen with a decrease in serum-calcium concentrations*** Manufacturer advises caution with use in patients with conditions that may worsen with a decrease in serum-calcium concentrations, including predisposition to QT-interval prolongation, history of seizures, and

	history of impaired cardiac function—serum-calcium concentration should be closely monitored. ***Switching from etelcalcetide*** Manufacturer advises that in patients who have discontinued etelcalcetide, do not initiate cinacalcet until at least three subsequent haemodialysis sessions are completed, and serum-calcium concentration is confirmed within normal range. *Lifestyle Interactions* Dose adjustment might be necessary if smoking started or stopped during treatment.
Reminder to ask patient about specific problems	Nausea, vomiting, dizziness, paraesthesia, headache, anorexia, symptoms of heart failure.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Manufacturer advises patients and their carers should be counselled on the symptoms of hypocalcaemia and importance of serum-calcium monitoring.
2. Manufacturer advises patients and carers should be counselled on the effects on driving and performance of skilled tasks—increased risk of dizziness and seizures.
3. Advise patient on side effects of cinacalcet.

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.

6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Consultants: Dr Bushra Ahmad Dr Karin Bradley Dr Natasha Thorogood Dr Rami Fikri Endocrine Specialist Nurses: Leigh Carroll-Moriarty Emily Lomas ..	DEPARTMENT OF DIABETES AND ENDOCRINOLOGY Bristol Royal Infirmary Marlborough Street Bristol BS2 8HW	Secretaries: 0117 342 7256 Endo CNS: 0117 342 6223 All consultants are available in working hours via the BRI switchboard (mobile) for urgent advice. In addition, an endocrine SpR is contactable in working hours via bleep 6216/ via switchboard. Alternatively, departmental email can be used and all are reviewed daily. If there is a problem on weekend, it is completely appropriate to simply omit the drug until the next working day.	Secretaries: Ubh-tr.diabetesandendoadmin@nhs.net Endo CNS: AdultEndocrineNurse@UHBristol.nhs.uk

Section 10: Document Details

Date prepared	July 2020
Prepared by	Samantha James - Specialist High Cost Drugs Pharmacist
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Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Click here to enter details

Section 12: References

Please list references

1. Milpharm, 2020. *Cinacalcet 30mg Film-coated tablets*. Available at: https://www.medicines.org.uk/emc/product/11483/smpc#CLINICAL_PRECAUTIONS [Accessed on: 07/07/2020].
2. Joint Formulary Committee, 2020. *British National Formulary*. Available at: https://bnf.nice.org.uk/drug/cinacalcet.html#patientAndCarerAdvice [Accessed on: 07/07/2020].
3. NICE Guidelines (2019) Hyperparathyroidism (Primary): diagnosis, assessment and initial management. Available at: www.nice.org.uk/guidance/ng132 [Accessed 20/08/20]
4. NHS England (2016) Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/06/ccp-cinacalcet-complex-primary-hyperparathyroidism-adults.pdf [Accessed 15/09/20]