Barking and Dagenham, Havering and Redbridge Clinical Commissioning Groups

TAKING PRIDE IN OUR CARE TOGETHER

Barking, Havering and Redbridge University Hospitals NHS Trust

BHR CCG's and BHRUT NHS Trust Shared Care Guidelines

CINACALCET FOR THE TREATMENT OF PRIMARY HYPERPARATHYROIDISM IN ADULTS WHEN PARATHYROID SURGERY IS CLINICALLY INAPPROPRIATE

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS AND FILED IN NOTES

Patient Full Name:	**NHS No:**
Date of Birth: `	**Hospital Number:**
Name of Referring Consultant:	**Contact number:**

INTRODUCTION

Primary hyperparathyroidism is a common disorder that is often diagnosed as a result of biochemical screening or as part of evaluation of decreased bone mass. It is normally seen with hypercalcaemia. Patients with symptomatic primary hyperparathyroidism should have surgery as parathyroidectomy is the only cure. This Shared Care guideline applies to patients with primary hyperparathyroidism who are unsuitable/ unfit for surgery.

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.

Cinacalcet is licensed for treatment of primary hyperparathyroidism when parathyroid surgery (parathyroidectomy) is clinically inappropriate (when corrected calcium levels are greater than 3.0 mmol/L).

Drug name	Indication	Oral Dose and administration

Guideline –adapted from mycophenolate guideline
Written by: Mohamad Rahman, Endocrine Pharmacist, Checked by Edel Casey- Clinical Lead Endocrine and Diabetes)
Date written: September 2020 Review date: September 2020
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Cinacalcet	**treatment of primary hyperparathyroidism when parathyroid surgery is clinically inappropriate**	30 mg –90mg twice daily (max up to 90mg QDS) 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.

Cautions

- Epilepsy
- Hepatic insufficiency
- Heart failure/ prolonged QT interval
- Pregnancy / breast-feeding
- Hereditary problems of galactose intolerance- Lapp lactase deficiency or glucose-galactose malabsorption.

Contra-indications

- Known hypersensitivity to the drug
- Hypocalcaemia

Drug Interactions

Caution is advised with substrates of CYP2D6 as levels and side-effects may be increased (e.g. flecainide, metoprolol, tricyclic antidepressants)

Warfarin is not affected by cinacalcet.

Cinacalcet is metabolised in part by the enzyme CYP3A4. Co-administration with inhibitors of CYP3A4 will cause an increase in cinacalcet levels. Dose adjustment of cinacalcet may be required if a patient receiving Cinalacet initiates or discontinues therapy with a strong inhibitor (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or inducer (e.g. rifampicin) of this enzyme.

Cinacalcet is also metabolised by CYP1A2 - cautious use of ciprofloxacin (CYP1A2 inhibitor) is advised. Smoking induces CYP1A2 and therefore dose adjustments may be required if the patient starts or stops smoking.

Close monitoring of the patient's smoking status is required and it is the responsibility of the patient to inform their clinician of any changes in smoking status during treatment.

GP's should refer the patient back to the consultant via Advice and Guidance for any changes in smoking status.

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For comprehensive information on cautions, contra-indications, adverse effects and interactions please refer to the current British National Formulary and Summary of Product Characteristics.

Prescribing in pregnancy and lactation

Pregnancy: Use within this group is not recommended unless it is under specialist advice- There is no data available for the use of cinacalcet within pregnant women. Although no direct harmful effects have been seen in pregnancy, parturition or postnatal development, use during pregnancy is not warranted unless the benefits outweigh the potential risks to the foetus.

Lactation: Use within this group is not recommended unless it is under specialist advice-. There have been no data to show the abundance of cinacalcet within human milk.

Patient's in this group will remain under the care of the consultant and not suitable for shared care.

Initiating baseline investigations and monitoring standards for Cinacalcet to be undertaken at BHRUT NHS Trust

Parameter	Blood Results	Action
Pre-treatment	Parathyroid hormone (PTH) Urea Electrolytes Creatinine Liver function tests (LFT) Calcium Phosphates Smoking status	Results to be known before drug is commenced
Monitoring	Monitor serum calcium levels within 1 week after initiation or dose adjustment. Once maintenance dose levels have been established, monitor serum calcium every 3 months. Consider discontinuation if relevant reductions in serum calcium are not maintained.	The aim of treatment is to maintain Adjusted Calcium between 2.2 and 2.8 mmol/l

Monitoring standards for Cinacalcet to be undertaken by GP

Parameter	Blood Results	Action	
Monitoring	Full Blood Count (FBC), LFT, Urea and Electrolytes (U&Es)	Every 6 months	
		Results	Action
		<2.2 mmol/l	*Stop the medication and refer back to the Endocrinologist.*

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	Monitor serum calcium* every 6 months (in between specialist annual review). Any concerns/queries contact endocrinologist on advice and guidance	*>2.8* mmol/l	*Refer back to the Endocrinologist for dose review.*

Adverse drug reactions ***For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF***		
Adverse event System, symptom/sign and frequency based on following convention: (Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000))	**Action to be taken** **Include whether drug should be stopped prior to contacting secondary care specialist**	**By whom**
Hypocalcaemia- Any signs of: paraesthesias, myalgias, cramping, tetany, prolonged QT, *arrhythmia* and convulsions *(common)*	*Stop drug*	*GP or consultant*
The patient should be advised to report any of the above signs or symptoms of hypocalcaemia to their GP as soon as possible.		
Worsening liver function	*Stop drug*	*GP or consultant*
Seizures- this may be secondary to hypocalcaemia leading to a reduction of seizure threshold	*Stop drug*	*GP or consultant*
Nausea and vomiting *– normally transient (common)*	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Dyspepsia, decreased appetite, anorexia *(common)*	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Constipation or diarrhoea *(common)*	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Hypersensitivity, rash *(common)*	*Stop*	*GP/ consultant*
Dizziness, headaches *(common)*	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Worsening heart failure, hypotension (unknown)	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Chest infection, cough, dyspnoea *(common)*	*Provide symptomatic relief. If symptoms persistent refer back to the specialist*	*GP*
Asthenia *(common)*	*If persistent – consult specialist*	*GP*
Hyperkalaemia *(common)*	*Treat. If severe and persistent then refer back to the specialist*	*GP*

CINACALCET

SHARED CARE

Sharing of care assumes communication between the specialist, GP and the patient. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

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SHARED CARE RESPONSIBILITIES

Consultant

1. Carry out baseline U&Es, calcium, phosphate and parathyroid hormone (PTH) levels in line with local and national guidelines/protocols.
2. Check current smoking status before commencing therapy and continue routine monitoring once commenced on treatment.
3. Adjust the dose of Cinacalcet as necessary according to clinical response.
4. Send a letter to the GP requesting shared care for this patient.
5. Initiate treatment and prescribe until patient is on a stable dose (minimum 1 month's treatment) and the GP formally agrees to shared care
6. Provide appropriate written or verbal information to patient, including the need for regular blood monitoring
7. Communicate promptly any changes in biochemistry monitoring and modification of cinacalcet dose to the GP.
8. Periodically (at six monthly intervals via telephone clinic) review the patient's clinical condition.
9. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition.
10. Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP
11. Advise GP on review, duration or discontinuation of treatment where necessary.
12. Inform GP of patients who do not attend clinic appointments within 2 weeks

General Practitioner

1. To agree to monitor and prescribe Cinacalcet in line with the shared care guideline once a stable dosing regime has been determined by secondary care.
2. Ensure no drug interactions with concomitant medicines including monitoring of patient's smoking status.
3. Monitor patient's overall health and well-being.
4. Report any adverse events to the consultant (where appropriate) and MHRA yellow card scheme.
5. Monitor serum calcium* every 6 months (in between specialist annual review).

CCG

1. To provide feedback to the Trust via Trust Medicines Optimisation Group
2. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
3. To support trusts in resolving issues that may arise as a result of shared care.

Patient

1. To take medication as directed by the prescriber, or to contact the GP if not taking medication.
2. To attend all appointments.
3. Failure to attend will result in medication being stopped (on specialist advice).
4. To read the patient information leaflet included with your medication and report adverse effects to their Specialist or GP.
5. Notify any change in smoking status to GP/ specialist

Costs

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Drug Product	March 2020: Drug tariff price
Cinacalcet 28 x 30mg tablets	£125.75
Cinacalcet 28 x 60mg tablets	£231.97
Cinacalcet 28 x 90mg tablets	£347.96

Contact Numbers for advice and support

Barking, Havering and Redbridge University Hospitals NHS Trust	
Consultant via switchboard Registrar on-call out of hours	Queens Hospital- 01708 435000 Bleep via switchboard
Endocrine Pharmacist	01708 435 000 (Extension 8164)
Pharmacy Medicines Information Department	01708 435 418
BHR CCG Medicines Management Team.	0208 822 3074

References

1. Mimpara (Cinacalcet®, Amgen Pharmaceuticals) Summary of Product Characteristics. January 2020
2. NHS England Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults
3. BNF online, accessed March 2020
4. Barts Health NHS Trust & local GPs - Cinacalcet For Primary Parathyroidism and Parathyroid Carcinoma in Adults- Shared Care
5. Shared Care Guideline for - Cinacalcet primary hyperparathyroidism- Pennine Acute Trust

Refer to the relevant BHR CCGs websites to obtain the latest version of this guideline

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APPENDIX 1

Barking, Havering and Redbridge University Hospitals NHS Trust
Cinacalcet Shared Monitoring Agreement Letter

Name of GP …… Address……

Drop code of GP ……..... ……..

Dear GP

Re: Patient's name……..…… Date of birth……...

Hospital number…… ……. NHS number……

Indication for treatment……..

Patient is on **Cinacalcet ……mg tablets**

Dose…… Frequency …….. Other Information (if appropriate) ……

This patient is being treated with Cinacalcet for the above condition-I hope that you will agree to share the care of this patient with the hospital.

Enclosed is a copy of the shared care monitoring guidelines for Cinacalcet to be retained in the patient's notes. It is safer for monitoring and prescribing to be done by the clinician. It is not possible for secondary care to do all the prescribing.

Should you agree to take over responsibility for monitoring, we will send a letter containing the details of the patient's treatment plan, the dose to be prescribed and all relevant blood results.

The patient has been given drug information regarding Cinacalcet	Please tick ☐
The patient has been initiated and is on a stable dose of treatment.	Please tick ☐
The patient has been counselled about the requirements for blood test monitoring	Please tick ☐
The patient has been advised to seek medical attention in the event of adverse reaction.	Please tick ☐

Please sign below and return this letter to the Hospital Specialist if you agree to take over shared care for this patient.

Many thanks

Signed (Hospital Doctor/ Specialist Nurse……

Name (print) ……Date……..

To be completed by GP and returned to hospital consultant

Please tick one box

□ I ACCEPT the proposed shared care arrangement for this patient
□ Or I ACCEPT the proposed shared care arrangement with the caveats below
□ Or I DO NOT ACCEPT the proposed shared care arrangement for this patient

My caveats / reason(s) for not accepting include

……
……
……
……

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Signed (GP)..... Name (print)…..... Date..……

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