CINACALCET SHARED CARE AGREEMENT (SCA) FOR ADULTS

FOR THE TREATMENT OF PRIMARY HYPERPARATHYROIDISM

SPECIALIST RESPONSIBILITIES

1. Assess patient, confirm diagnosis and discuss benefits and risks of treatment with the patient.
2. Perform pre-treatment assessments and on-going monitoring as detailed on page 3.
3. Prescribers should familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc/product/5599/smpc) or the BNF (https://bnf.nice.org.uk/
4. Initiate, titrate and stabilise treatment with cinacalcet therapy (usually up to 12 weeks). Please note patient response will affect time taken to reach a stable dose and some patients may reach a stable dose sooner.
5. Provide cinacalcet treatment for a further 4 weeks prior to transfer of treatment to Primary Care.
6. Provide appropriate written information on cinacalcet to the patient.
7. Review efficacy of treatment at regular intervals and ensure any drug treatment changes are communicated to the GP.
8. Act on pathology lab results if initiated by the hospital.
9. Advise the GP on frequency of monitoring and what to do if results are abnormal.
10. Communicate any changes in frequency of pathology testing to the GP if relevant.
11. Ensure clear back-up arrangements exist for GPs, including telephone number for advice and support and regularly checked e-mail account.
12. Discuss proposed SCA with the patient.
13. Send a letter to the patient's GP to request participation in the SCA, along with this current SCA and the clinic letter (containing full details of the prescribing and treatment plan). The GP must respond to the specialist within 14 days by signing this agreement and sending to the hospital.
14. Full clinical responsibility for the patient and the prescribed treatment will remain with the specialist if the GP declines to participate.

Once the GP has agreed to participate in the SCA, the specialist will:

1. Make a record in the patient's secondary care notes that treatment is being given as part of an SCA.
2. Inform the patient of the aspects of care that will be provided by the specialist and by the GP.
3. Ensure ongoing treatment is provided before prescribing is transferred.
4. Inform the patient when to contact their GP practice.
5. Ask the patient to report any adverse effects about their treatment to the specialist or GP. Adverse events should be reported by the specialist or GP to the MHRA (http://yellowcard.mhra.gov.uk/).
6. Review the patient as clinically appropriate and inform the GP of any changes to treatment.
7. Advise the GP of the on-going monitoring required as detailed on page 3.
8. Advise the GP of when and how to discontinue treatment (if necessary).
9. Ensure clear arrangements exist for GPs to obtain advice and support.

GP RESPONSIBILITIES

1. Review request from the specialist to participate in the SCA and respond to the specialist as soon as possible (within 14 days). To accept shared care please return a signed copy of this agreement to the specialist. Prescribing should not be refused on the grounds of drug cost.

Once shared care accepted, the GP will:

2. Make a record in the patient's primary care notes that treatment is being given as part of a SCA.
3. Familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc/product/5599/smpc) or the BNF (https://bnf.nice.org.uk.
4. Prescribe cinacalcet in accordance with the specialist prescribing and treatment plan.
5. Check for possible drug interactions when newly prescribing or stopping concurrent medication.
6. Report any adverse effects to the specialist and to the MHRA (http://yellowcard.mhra.gov.uk/).
7. Follow advice from the specialist regarding any changes required to treatment.
8. Perform on-going monitoring as advised by the specialist and detailed on page 3.

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9. Inform the patient's consultant if their smoking status changes.
10. Refer to the specialist if the patient's clinical condition deteriorates, if intolerance to treatment develops, or if contra-indications/cautions arise that prevent continued prescribing. Female patients must be asked to inform the specialist or GP if they are pregnant or planning a pregnancy.
11. Discontinue treatment (if necessary) on the advice of the specialist.
12. Contact the specialist for any necessary advice and support via the telephone helpline numbers provided.

Patient /Carers roles

1. Report any adverse effects to the specialist or GP whilst taking.
2. Report any changes in smoking status to the GP and/or specialist.
3. Share any concerns in relation to treatment with cinacalcet.
4. Participate in regular screening and monitoring.
5. Report to the specialist or GP if he or she does not have a clear understanding of their treatment.

ESNEFT Colchester Site Contact details	
Dr Bodmer (Consultant) Dr Vithian (Consultant) Catherine Gouveia	Endocrinology Department endocrineadmin.colch@esenft.co.uk 01206 742514 and 742511. Advice and guidance on NHS e-referrals
ESNEFT Ipswich Site Contact details	
Dr Craig Parkinson Dr Sanjeev Sharma Dr Duncan Fowler Dr Damian Morris Dr Zeenat Banu	Endocrinology Department IHTDiabetesandEndocrine@esneft.nhs.uk Advice and guidance on NHS e-referrals
West Suffolk Hospital Foundation Trust Contact Details	
Dr J Clark Dr J Majeed Dr N Wijenaike Dr A Brahma Dr H Marath Dr J Jayaweera Dr E Soong	Endocrinology Department diabetes.endocrine@wsh.nhs.uk Advice and guidance on NHS e-referrals

GP to complete and return to specialist within 14 days	
Patient name:	
Date of birth:	
Hospital Number:	
GP name	
GP signature to accept shared care:	
Date	

Note the reference below. These guidelines are being used locally to monitor therapy.

- SSC 2035: Cinacalcet for complex primary hyperparathyroidism in adults- clarification on tariff and advice on shared care arrangements. Reference letter: July 2019
- Clinical Commissioning Policy: Cinacalcet for complex primary hyperparathyroidism in adults https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-a/a03/

SHARED SPECIALIST & GP RESPONSIBILITIES: MONITORING

On-going monitoring will be transferred from the specialist to the GP after the specialist has stabilised the patient on treatment

	Parameter		• Frequency	
	In addition to absolute values for haematological indices, a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance			
Secondary Care Specialist	**Baseline tests:** Urea and Electrolytes Creatinine Calcium Phosphates Smoking status Parathyroid hormone (PTH)	• Prior to treatment (Cinacalcet treatment should not be initiated in patients with a serum calcium (corrected for albumin) below the lower limit of the normal range) • Adjusted calcium should be measured within 1-2weeks of initiation or dose adjustment of cinacalcet (the SPC states within 1 week but local practice allows a little longer)		
	Parameter	**Frequency**	**Action to take if abnormal result**	
Specialist moving to GP once shared care accepted	Adjusted calcium	• Every 6 months* once treatment stabilised • Calcium levels to be taken within 1 week of dose adjustments	Adjusted calcium level <2.4mmol/L	Reduce dose of cinacalcet by 30mg per day (if on 30mg od, reduce to 30mg every second day) and seek further advice from the secondary care Specialist
			Adjusted calcium level between 2.4 and 2.75mmol/L	Dose adequate, continue current dose
			Adjusted calcium level >2.75mmol/L to 2.85	Seek advice from secondary care specialist likely dose will be left unaltered
			Adjusted calcium level >2.85mmol/L	Increase dose of cinacalcet by 30mg per day and seek advice from secondary care specialist
	Urea & Electrolytes (U&Es)	Every 6 months once treatment stabilised	Abnormal U+Es for patients who are not within the desired range of calcium between 2.2 to 2.75mmol/L should be highlighted when seeking specialist advice on management for patients with calcium levels outside of this range.	
	Symptoms to be reported by patient (see patient roles) or asked where appropriate		**Action for GP to take if symptom occurs/reported**	
Specialist and GP	Any signs of hypocalcaemia: paraesthesias, myalgias, cramping, tetany, prolonged QT, arrhythmia and convulsions		• Stop cinacalcet therapy and contact specialist for further advice	
	GI disturbances: nausea and vomiting, dyspepsia, constipation, diarrhoea		• Provide appropriate symptomatic relief as required. If symptoms persistent, contact specialist for further advice	
	Hypersensitivity / rash		• Stop cinacalcet therapy and contact specialist for further advice	
	Dizziness, headache		• Provide symptomatic relief. If symptoms persistent, contact specialist for further advice	
	Changes in smoking status		• Undertake calcium levels and follow advice above if results are abnormal	

*Please note while the BNF/manufacturer suggest 2-3 monthly monitoring endocrinologists across the region have agreed upon 6 monthly monitoring as no further clinical value is demonstrated with a higher frequency of monitoring

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