

SHARED CARE AGREEMENT



Name of medicine Cinacalcet

Indication

Treatment of secondary hyperparathyroidism in patients with end stage renal disease on dialysis

Version: 1.0

Approval date: **October 2015**

Review date: **October 2018**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Policy and Procedures for the Shared Care of Medicines, available at:

<https://org.nhslothian.scot/Committees/ADTC/MedicinesGovernancePoliciesADTCPolicyStatements/>

Roles and Responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Assessment of the need for cinacalcet.
- Monitoring of serum electrolyte levels including parathyroid hormone levels and calcium and phosphate before initiation.
- Initiate treatment at a dose at 30mg cinacalcet once daily.
In most cases, the initial 4 week supply will be provided by the specialist service. However, on occasions, when initiation of treatment is not considered to be urgent, the specialist may request that the GP prescribes the initial supply.
- Communicating advice on dose changes to the patient and GP.
- Review the efficacy of treatment within 4 months of initiation – treatment will be continued only if a reduction in the plasma concentration of intact parathyroid hormone of 30% or greater is seen, in line with NICE guidance. Advice on whether to continue cinacalcet will be communicated to the patient and GP.

General Practitioner

- Prescribing of cinacalcet after initial decision to treat.
- Monitoring of adverse effects and communicating to consultant e.g. low calcium.

Patient, relatives, carers

As listed in NHS Lothian Policy and Procedures for the Shared Care of Medicines

Support and Advice for the GP

Contact Points

Specialist Team Numbers

Renal Unit Ward Tel: 0131 242 2061

Renal Ward 206 Doctors Room Tel: 0131 242 1217

Renal Pharmacist Tel: 0131 242 1000 Bleep 8006 or 5745

Pharmacy Medicines Information Tel: 0131 242 2920

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication

Cinacalcet is a calcimimetic which acts directly on the parathyroid gland to reduce parathyroid hormone levels thereby reducing serum calcium and phosphate to control renal bone disease.

For further information, please refer to NICE Technology Appraisal 117 'Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy' <https://www.nice.org.uk/guidance/ta117>

Indication

Cinacalcet is licensed for the treatment of secondary hyperparathyroidism in patients with end stage renal disease on dialysis therapy. Patients matching the following criteria will be considered suitable for cinacalcet therapy:

Refractory secondary hyperparathyroidism in patients with end stage renal disease (including those with calciphylaxis) where:

- a) plasma level of parathyroid hormone (PTH) is uncontrolled, defined as greater than 85 picomol/L (800pg/ml) and is refractory to standard therapy, and a normal or high adjusted serum calcium
and
- b) surgical parathyroidectomy is contraindicated in that the risks of surgery outweigh the benefits.

Dosage and Administration

Cinacalcet will be started at a dose of 30mg once daily (preferably taken with the evening meal)

The dose should be titrated every 2-4 weeks to a maximum of 180mg daily aiming for plasma parathyroid level of 15.9-31.8pmol/l (150-300pg/ml). The renal specialist will advise on dose changes as appropriate.

Response to treatment should be monitored regularly (see below) and treatment should be continued only if a reduction in the plasma levels of intact parathyroid hormone of 30% or more is seen within 4 months of treatment, including dose escalation as appropriate.

Monitoring

NB: Blood is taken during dialysis sessions for the tests listed below. The renal specialists will monitor the results of the blood tests and recommend changes in cinacalcet dosage based on PTH and calcium levels.

If additional blood tests are required out with those taken in hospital this will be discussed with the GP.

Test	Frequency	Abnormal Result	Action if Abnormal Result
Parathyroid hormone (PTH) The levels should be assessed at least 12 hours after dosing with cinacalcet (making evening dosing ideal)	<u>Initiation and dose changes:</u> Check every 1-4 weeks <u>Maintenance therapy:</u> Check every 1-3 months	Hospital Consultant will monitor PTH levels	Hospital Consultant will monitor PTH levels and take any action required
Corrected Calcium (CorrCa)	<u>Initiation and dose changes:</u> Check within 1 week of initiation or dose adjustment <u>Maintenance therapy:</u> Check approximately every month.	CorrCa levels decrease below the normal range (2.1mmol/l)	Levels will be monitored by the hospital consultant. Discuss with the hospital consultant if there are any concerns.

Cautions, contraindications - Refer to current Summary of Product Characteristics (SPC):

www.medicines.org.uk

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk