NHS

# DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
# SHARED CARE AGREEMENT
# Cinacalcet in primary hyperparathyroidism

## 1. REFERRAL CRITERIA

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable.
- Patients will only be referred to the GP once the GP has agreed in each individual case.
- When transfer agreed the patient will be given a supply of cincalcet sufficient for 4 weeks maintenance therapy.

## 2. AREAS OF RESPONSIBILITY

| GP's responsibilities | Consultant responsibilities |
|---|---|
| **1.** To agree to prescribing cinacalcet in line with the shared care guideline once a stable dosing regime has been determined by secondary care.<br>**2.** Seeking advice from secondary care if there is a significant change in the health status of the patient.<br>**3.** Reporting adverse reactions to the hospital consultant or respiratory nurse specialist, and community pharmacist<br>**4.** Reducing/stopping/increasing/adding and/or altering treatment as requested by the secondary care clinician.<br>**5.** Monitor serum calcium* every 6 months (in between specialist annual review). For advice on abnormal calcium levels see section 4v<br>**6.** To report any adverse effects to the referring specialist and the MHRA yellow card scheme | **1.** Initiation and prescribing of cinacalcet until patient is stabilised on the optimal dose.<br>**2.** Monitoring the patient for response and any adverse drug reactions (ADR) during the initiation period.<br>**3.** To make arrangements for annual monitoring of PTH* and bone profile (including calcium) in secondary care once a stable dose is established<br>**4.** Liaising with the patient's GP to agree shared care using the letter in appendix 1<br>**5.** Outlining to the GP when treatment should be discontinued if no improvement in the patient's condition is seen.<br>**6.** Evaluation of ADR and other concerns reported by the GP related to the use of cinacalcet by the patient.<br>**7.** For patients treated for hypercalcaemia awaiting surgery give GPs clear notification of anticipated surgery date to inform prescribing duration<br>**8.** To report any adverse effects to the MHRA yellow card scheme and GP |
| ***Agreed with local endocrinologists** | |
| **Patient responsibilities** | |
| • Report any adverse effects to the specialist or GP whilst taking cinacalcet<br>• Share any concerns in relation to treatment with cinacalcet<br>• Report to the specialist or GP if they do not have a clear understanding of their treatment | |

## 3. COMMUNICATION AND SUPPORT

| Chesterfield Royal Hospital | Royal Derby Hospital |
|---|---|
| Consultant Physician as named on discharge letter<br>**Telephone No:** 01246 277271<br><br>**Out of hours contacts:**<br>Contact the on-call Medic for the relevant speciality via switchboard: 01246 277271 | Consultant Endocrinologist as per clinic correspondence or discharge summary<br>Dr Stanworth/Dr Idris: 01332 783283<br>Dr Ali/ Dr King: 01332 783284<br>Dr Sugunendran: 01332 783286<br>Dr Hughes: 01332 787696<br><br>**Out of hours contacts:**<br>Pharmacy, DTHFT, ask for on-call pharmacist via switchboard: 01332 340131 |

## 4. CLINICAL INFORMATION

| | |
|---|---|
| **i. Prescribed indications** | Cinacalcet is indicated for :<br>1. The treatment of acute hypercalcaemia symptomatic with calcium between 2.85-3.00mmol/ L or biochemically severe hypercalcaemia calcium >3.0mmol/l due to Primary Hyperparathyroidism, when parathyroidectomy is contraindicated or not clinically appropriate , and will avoid the need for further admission to |

<table>
<tr><td></td><td>hospital. (NHSE commissioning policy)<br>2. The treatment of hypercalcaemia (Ca >3.0mm/l) in patients who are significantly symptomatic and awaiting surgery.</td></tr>
<tr><td>ii. Dose & route of administration</td><td>The usual dose of cinacalcet is between 30-60mg twice daily. The calcium lowering effect is substantially present within two to three weeks (85-90%) after initiating therapy with 30mg twice daily. In patients whose serum calcium is not adequately controlled, the dose may be increased to 90mg FOUR times daily.<br>Cinacalcet should be taken with or after food, preferably at the same time each day.</td></tr>
<tr><td>iii. Adverse effects</td><td>The most frequently reported adverse events are nausea and vomiting, rash, hypersensitivity, dizziness and myalgia. Isolated cases of hypotension, worsening heart failure and arrhythmia also reported.</td></tr>
<tr><td>iv. Monitoring Requirements</td><td>Baseline biochemical monitoring will be undertaken by the specialist in addition to all ongoing routine blood monitoring as described as part of the diagnosis and management of the condition (unless specifically agreed with the GP)<br><br>Serum calcium 1 week after initiation or dose adjustment. After maintenance dose has been established, levels should be measured every 6 months<br><br>The aim of treatment is to maintain adj Ca at between 2.50 and 2.80 mmol/l. See section 4v for advice on action to be taken if calcium levels become abnormal</td></tr>
<tr><td>v. Action to be taken</td><td>If calcium levels become abnormal during treatment the Consultant should be notified in each case. If marginally out of range repeat test before action.<br><br>
<table>
<tr><th>Calcium level</th><th>Action for GPs</th></tr>
<tr><td>> 2.80</td><td>Check compliance seek specialist advice as patient will require dose increase</td></tr>
<tr><td>2.20 – 2.50</td><td>Check compliance. Seek specialist advice as patient will likely require dose reduction</td></tr>
<tr><td>< 2.20</td><td>Stop cinacalcet, recheck calcium after one week. Seek specialist advice, likely resume at significantly lower dose</td></tr>
</table></td></tr>
<tr><td>vi. Clinically relevant drug interactions</td><td>Caution is advised with substrates of CYP2D6 as levels and side-effects may be increased (e.g. flecainide, metoprolol, tricyclic antidepressants)<br><br>Warfarin is not affected by cinacalcet.<br><br>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 Mimpara may be required if a patient receiving Mimpara initiates or discontinues therapy with a strong inhibitor (e.g. ketoconazole, itraconazole, telithromycin, voriconazole, ritonavir) or inducer (e.g. rifampicin) of this enzyme.<br><br>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 during cinacalcet treatment.</td></tr>
<tr><td>vii. Contraindications</td><td>Cinacalcet is contraindicated:<br>• Known hypersensitivity to the drug or any of the excipients<br>• Pregnancy<br>• Breast-feeding<br>Cinacalcet should be used with caution in:<br>• Epilepsy<br>• Hepatic insufficiency<br>• Heart failure/ prolonged QT interval</td></tr>
<tr><td>viii. Supply, storage and reconstitution instructions</td><td>Can be stored at room temperature and just need to avoid excessive direct sunlight exposure.</td></tr>
<tr><td>ix. Prepared/ reviewed by</td><td>Martin Shepherd, Head of Medicines Management, Chesterfield Royal Hospital<br>Dr. Shillo Consultant endocrinology and metabolic medicines CRHFT<br>Dr Roger Stanworth, Consultant Endocrinologist, University Hospitals of Derby and Burton NHS Foundation Trust</td></tr>
</table>

## Appendix 1

***{Insert Hospital Logo here}***

Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

**PRIVATE & CONFIDENTIAL**
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_ADDRESS_4»
«GP_POSTCODE»

**DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER**

Dear «GP_TITLE» «GP_SURNAME»

**«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»**
**«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3»**
**«CURRENT_ADDRESS_4» «CURRENT_POSTCODE»**

Your patient was seen on ***{Insert date}*** with a diagnosis of ***{Insert diagnosis}***. I have initiated the following medication ***{Insert drug name}*** and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

| Dose Regimen | Date ***{Insert medicine name}*** started | Date for GP to start prescribing ***{Insert medicine name}*** from |
|---|---|---|
| | | |
| The baseline test results are (if applicable): | | |

I can confirm that the following has happened with regard to this treatment:

| | **Specialist to complete** |
|---|---|
| *The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:* | |
| *Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory* | *Yes / No* |
| *The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care* | *Yes / No* |
| *The risks and benefits of treatment have been explained to the patient* | *Yes / No* |
| *The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed* | *Yes / No* |
| *The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments* | *Yes / No* |
| *I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)* | *Yes / No* |

| | |
|---|---|
| *I have included with the letter copies of the information the patient has received* | *Yes / No* |
| *I have provided the patient with sufficient medication to last until* | |
| *I have arranged a follow up with this patient in the following timescale* | |

If you do **NOT** wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

**{Consultant name}**

## GP RESPONSE TO SHARED CARE (only complete & send if **NOT** participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

| Patient: | NHS No: |
|---|---|
| Consultant: | Medicine requested for shared care: |

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

| | | Tick which apply |
|---|---|---|
| 1. | **The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care**<br>As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.<br>**I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.** | |
| 2. | **The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement**<br>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.<br>**Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you** | |
| 3. | **A minimum duration of supply by the initiating clinician**<br>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.<br>***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.*** | |
| 4. | **Initiation and optimisation by the initiating specialist**<br>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.<br>***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.*** | |
| 5. | **Shared Care Protocol not received**<br>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.<br>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.<br>***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.*** | |
| 6. | **Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)** | |

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possibl

Yours sincerely

{GP name}
{Surgery}

**Please send a copy of this response to:**

1. The specialist/consultant requesting shared care
2. **AN ANONYMISED COPY OF THIS FORM ONLY** to the Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

***(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).***