DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)  
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 cinacalcet sufficient for 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

<table>
<thead>
<tr>
<th>GP’s responsibilities</th>
<th>Consultant responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>To agree to prescribing cinacalcet in line with the shared care guideline once a stable dosing regime has been determined by secondary care.</td>
<td>Initiation and prescribing of cinacalcet until patient is stabilised on the optimal dose.</td>
</tr>
<tr>
<td>Seeking advice from secondary care if there is a significant change in the health status of the patient.</td>
<td>Monitoring the patient for response and any adverse drug reactions (ADR) during the initiation period.</td>
</tr>
<tr>
<td>Reporting adverse reactions to the hospital consultant or respiratory nurse specialist, and community pharmacist</td>
<td>To make arrangements for annual monitoring of PTH* and bone profile in secondary care once a stable dose is established</td>
</tr>
<tr>
<td>Reducing/stopping/increasing/adding and/or altering treatment as requested by the secondary care clinician.</td>
<td>Liaising with the patient’s GP to agree shared care using the letter in appendix 1</td>
</tr>
<tr>
<td>Monitor serum calcium* every 6 months. For advice on abnormal calcium levels see section 4v</td>
<td>Outlining to the GP when treatment should be discontinued if no improvement in the patient’s condition is seen.</td>
</tr>
<tr>
<td>To report any adverse effects to the referring specialist and the MHRA yellow card scheme</td>
<td>Evaluation of ADR and other concerns reported by the GP related to the use of cinacalcet by the patient.</td>
</tr>
</tbody>
</table>

*Agreed with local endocrinologists

Patient responsibilities
- Report any adverse effects to the specialist or GP whilst taking cinacalcet
- Share any concerns in relation to treatment with cinacalcet
- Report to the specialist or GP if they do not have a clear understanding of their treatment

3. COMMUNICATION AND SUPPORT

Chesterfield Royal Hospital
Consultant Physician as named on discharge letter
Telephone No: 01246 277271

Royal Derby Hospital
Consultant Endocrinologist as per clinic correspondence or discharge summary
Dr Stanworth/ Dr Idris 01332 783283
Dr Ali/ Dr King 01332 783284
Dr Sugunendran 01332 783286
Dr Hughes 01332 787696

4. CLINICAL INFORMATION

i. Prescribed indications
   Cinacalcet is indicated for:
   1. The treatment of acute 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 hospital.
   2. The treatment of hypercalcaemia (Ca >3.0mmol/l) in patients who are significantly symptomatic and awaiting surgery.

ii. Dose & route of administration
   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. Cinacalcet should be taken with or after food, preferably at the same time each day.
iii. Adverse effects
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.

iv. Monitoring Requirements
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)

Serum calcium 1 week after initiation or dose adjustment. After maintenance dose has been established, levels should be measured every 6 months

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

v. Action to be taken
If calcium levels become abnormal during treatment the Consultant should be notified in each case. If marginally out of range repeat test before action.

<table>
<thead>
<tr>
<th>Calcium level</th>
<th>Action for GPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 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>&lt; 2.20</td>
<td>Stop cinacalcet, recheck calcium after one week. Seek specialist advice, likely resume at significantly lower dose</td>
</tr>
</tbody>
</table>

vi. Clinically relevant 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 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.

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.

vii. Contraindications
Cinacalcet is contraindicated:
- Known hypersensitivity to the drug or any of the excipients
- Pregnancy
- Breast-feeding
Cinacalcet should be used with caution in:
- Epilepsy
- Hepatic insufficiency
- Heart failure/ prolonged QT interval

viii. Supply, storage and reconstitution instructions
Can be stored at room temperature and just need to avoid excessive direct sunlight exposure.

ix. Prepared by
Martin Shepherd, Head of Medicines Management, Chesterfield Royal Hospital
Dr Roger Stanworth, Consultant Endocrinologist, Derby Hospitals NHS Foundation Trust

This does not replace the summary of product characteristics, which should be read in conjunction with it.
Date Prepared: January 2015  Reviewed: May 2017  Review Date: April 2019
PRIVATE & CONFIDENTIAL

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

{Insert date}

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.

<table>
<thead>
<tr>
<th>Dose Regimen</th>
<th>Date {Insert medicine name} started</th>
<th>Date for GP to start prescribing {Insert medicine name} from</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

The baseline test results are (if applicable):

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted the need for monitoring, how monitoring will be arranged, and the roles of the consultant / nurse specialist, GP and the patient in shared care. I confirm the patient has understood and is satisfied with this shared care arrangement at this time.

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.

<table>
<thead>
<tr>
<th>Patient:</th>
<th>NHS No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consult:</td>
<td>Medicine requested for shared care:</td>
</tr>
</tbody>
</table>

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:

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 Clinical Effectiveness Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: sderccg.derbyshiremedicinesmanagement@nhs.net

(Sending a copy of this form to the Clinical Effectiveness 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).