Berkshire West Integrated Care System
Representing
Berkshire West Clinical Commisioning Group
Royal Berkshire NHS Foundation Trust
Berkshire Healthcare NHS Foundation Trust
Berkshire West Primary Care Alliance

Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from ***Secondary Care to Primary Care***

Cinacalcet for the treatment of secondary hyperparathyroidism

APC PG 005

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Date
Drugs & Therapeutics Committee	Sakeb Hussain, DTC Chair	December 2018
Area Prescribing Committee	APC Chair	January 2019
GP MOC	GP MOC Chair	January 2019

Change History

Version	Date	Author	Reason
v.1.3	26/10/18	Lindsay Yap	Update to new template

This prescribing guideline remains open to review considering any new evidence.

Author	Lindsay Yap	Date of production:	26.10.2018
Job Title	Lead Pharmacist – Renal & Gastro	Review Date	
Protocol Lead	Dr Mobin Mohteshamzedeh, Consultant Nephrologist	Version	V 1.3

Principles of Prescribing Arrangement

These prescribing Guidelines are a local policy to enable General Practitioners to accept responsibility for the prescribing and monitoring of medicines, treatments or devices in primary care, in agreement with the initiating specialist service.

This guideline provides a framework for the seamless transfer of care for a person from a hospital or specialist service setting to general practice, where this is appropriate and in the patient's best interest. People should never be placed in a position where they are unable to obtain the medicines they need because of a lack of communication between primary and secondary care.

It is important to note, in line with the General Medical Council guidance on prescribing, doctors are responsible for prescriptions they sign, and their decisions and actions when they supply and administers medicines and devices; or authorise or instruct others to do so.

Transfer of care

Transfer of clinical responsibility to primary care should only be considered where the patient's clinical condition is stable or predictable.

Referral to the GP should only take place once the GP has agreed to this in **each individual case**, and the hospital or specialist will continue to provide prescriptions until a successful transfer of responsibilities. The GP should confirm the agreement and acceptance of the shared care prescribing arrangement and that supply arrangements have been finalised. The secondary care provider must supply an adequate amount of the medication to cover this transition period. The patient should then be informed to obtain further prescriptions from the GP.

Clinicians should clearly explain what a shared care arrangement means for the patient and why it might be an option in their case. The patient or their carers should have the opportunity to ask questions and explore other options if they don't feel confident that shared care will work for them. They should be fully involved in, and in agreement with, the decisions to move to a shared care model for their on-going care. **Importantly, patients should never be used as a conduit for informing the GP that the prescribing is to be transferred.**

Patient consent

The best interest, agreement and preferences of the patient should be at the centre of the decision to begin shared care and their wishes followed wherever possible. Patients should be able to decline shared care if, after due consideration of the options, they decide that it is not in their best interests. Involvement of carers may be critical, especially in circumstances when it is not possible for the patients to make a decision e.g. mental capacity; where appropriate they should be included in the discussion about shared care.

Background

Cinacalcet is used to treat secondary hyperparathyroidism in patients with end stage renal disease on dialysis therapy.

Secondary hyperparathyroidism is associated with increases in parathyroid hormone (PTH) and disturbances in mineral metabolism. The goals of treatment are to lower PTH levels, maintain normal calcium and phosphorous levels, prevent progressive bone resorption and the systemic consequences of elevated serum calcium and phosphate.

Cinacalcet directly lowers PTH levels by increasing the sensitivity of the calcium receptors to extracellular calcium.

This document should be used alongside guidance published by the National Institute for Health and Clinical Excellence (TA 117 Jan 2007). NICE recommends that cinacalcet for treatment of refractory hyperparathyroidism in patients with end-stage renal disease (including those with calciphylaxis) in those:

- who have very uncontrolled plasma levels of intact PTH (defined as > 85pmol/l or 800pg/ml that are refractory to standard therapy, and a normal or high adjusted serum calcium level, and
- in whom surgical parathyroidectomy is contra-indicated, in that risks of surgery are considered to outweigh the benefits.

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

Responsibilities

Specialist Team Responsibilities (Nephrology Consultant)

General Responsibilities

- Confirm patient's secondary hyperparathyroidism.
- Confirm patient's suitability for cinacalcet treatment
- Where patient is suitable for treatment with cinacalcet**,** ensure the process of shared care has been explained to the patient and they give their informed consent to the transfer of care to their GP
- Initiate the patient on cinacalcet and arrange for follow-up appointments (via outpatient clinic/virtual clinics) to manage dose titration and appropriate monitoring
- Ensure the patient is reviewed monthly after dose optimisation and discontinue cinacalcet treatment if there is no improvement in symptoms
- Any dose changes once the patient is established on treatment will be conveyed in writing to the GP for the GP to prescribe
- Monitor side effects of medication via routine follow up
- Report adverse events to the CHM/MHRA
- Check drug interactions with any current medication the patient is taking
- Supply the patient with enough cinacalcet (via RBH Outpatient Pharmacy) to cover the period of transfer to the GP. This needs to take in to account the period for the GP to accept the request
- If the GP does not accept the request to take prescribing responsibility, continuing treatment must be prescribed by the Specialist team.

Transfer of Prescribing Responsibilities

- Transfer of clinical responsibility to primary care should only be considered where the person's clinical condition is stable or predictable.
- Communicate to the patient's GP to request a transfer of prescribing responsibilities; detailing the drug, formulation, dose and frequency to be prescribed, along with details of how to refer to the nephrology team should the patient develop a problem with their treatment.

Disease Monitoring

- The patient will be reviewed by the Specialist Team when necessary. The time interval will differ depending on the individual patient.
- Communicate to the GP all necessary monitoring that needs to be carried out in primary care (detailed below).

Primary Care Team Responsibilities (General Practitioner)

- The GP will add the drug to the patient's repeat prescription within 2 weeks of receipt of the information from the nephrologist and issue on-going prescriptions.
- Check drug interactions with any new medication started or any new conditions diagnosed. Contact the specialist team if possible interactions found and discuss with Consultant.
- Undertake drug specific monitoring, where applicable, as detailed below.
- Amend prescription as per requests from secondary care for dose changes in patients on established treatment.
- Where a change in medication or dose is required, for example if a drug/dose has not been tolerated, the following procedure will be followed:
  - **[Enter details of process i.e.]**
  - **GP/Patient to contact Clinical Nurse Specialist will liaise with Consultant to decide on a suitable alternative dose.**
  - **Clinical Nurse Specialist will send a written request to ask GP to issue a prescription, detailing individual patient plan including dose titration or the need to discontinue treatment (where applicable).**
- Report adverse events to the CHM/MHRA.
- Report adverse events to the consultant sharing the care of the patient.

Patient's role (or that of carer)

- Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment.
- Tell the specialist or GP of any other medication being taken, including over-the-counter products.
- Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP
- Adhere to treatment as advised by the specialist.

Communication

Specialist to GP
The Consultant/Nurse will inform the GP when they have initiated cinacalcet and will provide a summary of dosage / instructions for the GP to follow.

GP to Specialist
If the GP has concerns over the prescribing of the relevant cinacalcet, they will contact the nephrology team as soon as possible.

Contact Information

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Lead Consultant	Dr Mobin Mohteshamzadeh
Lead Nurse	Angela Clarke

References

1. NHS England. 2018. *Responsibility for prescribing between Primary & Secondary/Tertiary Care. Accessed via https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ on 16/3/2018.*

2. NICE TA 117. Published January 2007. Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. Accessed via https://www.nice.org.uk/guidance/ta117 on 26/10/18.