NHS
Derby and Derbyshire
Integrated Care Board

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

Guideline on prescribing and monitoring of Cinacalcet for Primary Hyperparathyroidism

Taking **personalised approaches** is a key approach to provide best care.

- Enabling **choice**, ensures that patients are aware of their options.
- **Shared decision making** helps patients to make decisions that are right for them.
- Supporting **self-management** increases people's knowledge, skills and confidence to manage their own health and care.
- Giving information in a **health literate** way means that people will understand how to manage their health.

Further information about offering choice, shared decision making and supporting self-care can be found here.

JAPC has relaxed traffic light classification of cinacalcet for hyperparathyroidism from Amber (shared care) to **GREEN** after specialist initiation.

Background- ongoing monitoring for hyperparathyroidism

Once initial assessment and diagnosis have been undertaken, ongoing monitoring in people with asymptomatic primary hyperparathyroidism may be done in primary care.

This includes patients who have been initiated and stabilised on cinacalcet, as generally their condition will be stable, similar to the average patient with primary hyperparathyroidism. Acute calcium derangements in these patients are rare, with the exceptions of poor compliance with cinacalcet or clinical dehydration.

See also Derbyshire Shared care pathology guideline for the management of primary hyperparathyroidism.

Primary Care Monitoring after stable therapeutic dose of cinacalcet

Parameter	Frequency	comment
Serum calcium	every 12 months. Specialist may advise extra monitoring on a case-by-case basis to be agreed with GP	drug monitoring
renal function	every 12 months	disease monitoring
blood pressure	every 12 months	disease monitoring
Bone mineral density (if appropriate)	every 3-5 years or according to instructions at the time of discharge from endocrine clinic	disease monitoring

Cinacalcet prescribing information

Indication	• Symptomatic hypercalcaemia with calcium between 2.85-3.00mmol/L • biochemically severe hypercalcaemia calcium >3.0mmol/l, when parathyroidectomy is contraindicated or not clinically appropriate, or in patients who are significantly symptomatic and awaiting surgery.

Dosing	• The usual dose is between 30-60mg twice daily (with or without food). • The calcium lowering effect is substantially present (85-90%) within 2-3 weeks after initiating therapy with 30mg twice daily. • In patients whose serum calcium is not adequately controlled, the dose may be increased up to 90mg four times daily.
Contraindications	Cinacalcet is contraindicated in patients with hypocalcaemia and those with sensitivities to the active substance or to any of the excipients.
Caution	Manufacturer advises caution with use in patients with conditions that may worsen with a decrease in serum-calcium concentrations, including • predisposition to QT-interval prolongation • history of seizures, and • history of impaired cardiac function—serum-calcium concentration should be closely monitored. Seek specialist advice if patient becomes pregnant
Adverse events	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. *Seek guidance via A&G if symptoms persist*
Interaction (list not exhaustive, see BNF/SPC for further detail)	• Concurrent administration of other medicinal products known to reduce serum calcium may result in an increased risk of hypocalcaemia. • Cinacalcet is metabolised in part through cytochrome P450 enzymes CYP3A4 and CYP1A2 o Smoking induces CYP1A2 and therefore dose adjustments may be required if the patient starts or stops smoking during cinacalcet treatment. o Dose adjustment may be required if a patient receiving cinacalcet initiates or discontinues therapy with a strong inhibitor (e.g. azoles, telithromycin, ritanovir) or inducer (e.g. rifampicin) of CYP3A4. • Cinacalcet is predicted to increase the exposure to amitriptyline, clomipramine, dosulepin, doxepin, imipramine, lofepramine, nortriptyline & trimipramine. Manufacturer advises monitor for toxicity and adjust dose as necessary. • Cinacalcet is predicted to markedly increase the exposure to atomoxetine. Manufacturer advises adjust dose. • Cinacalcet is predicted to decrease the efficacy of tamoxifen. Manufacturer advises avoid. *If dose adjustment required seek specialist advice via A&G*

Specialist responsibilities

- Baseline biochemical monitoring will be undertaken by the specialist including serum calcium 1 week after initiation or dose adjustment. Specialist will initiate and titrate cinacalcet until patient is stabilised on the optimal dose.
- **Specialist should communicate to GP clearly the expected length of treatment** and any additional monitoring required such as measuring bone mineral density every 3-5 years.

GP responsibilities

- GP can continue to prescribe cinacalcet in primary care following initiation and stabilisation of treatment by specialist.
- After maintenance dose has been established, carry out monitoring as outlined above. Calcium levels should be measured every 12 months. The aim of treatment is to **maintain adjusted Calcium level at between 2.50 and 2.80 mmol/l.**
- If calcium levels become abnormal during treatment GP should seek specialist advice via advice and guidance (A&G)- this would be expected necessary for the majority of patients with calcium levels out of target range, but if there is a clear reason for the out of range result (e.g. temporary loss of treatment compliance) or if the result is only marginally abnormal (e.g. within 0.05 mmol/l of target) and patient has previous stable levels on current cinacalcet dose, then a repeat test after 2-3 week interval before seeking advice is reasonable.

Adj. Ca	Action for GPs
> 2.80	Check compliance; Seek specialist advice as patient will require dose increase
2.20 – 2.50	Check compliance; Seek specialist advice as patient will likely require dose reduction
< 2.20	Stop cinacalcet, recheck calcium after one week. Seek specialist advice, likely resume at significantly lower dose

Advice and Guidance – endocrinology

UHDB
Endocrinology secretary dhft.diabandendosecs@nhs.net 01332 783283
CRH
Consultant Endocrinologist as named on discharge letter Telephone No (sec): 01246 513104

Reference

NICE NG132 Hyperparathyroidism (primary): diagnosis, assessment and initial management (2019) https://www.nice.org.uk/guidance/ng132 accessed 20/4/2022
Derbyshire JAPC shared care agreement cinacalcet in primary hyperparathyroidism.

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