Greater Manchester Guidelines on the Management of Chronic Kidney Disease - Mineral Bone Disorder (CKD-MBD)

Classification: Clinical Guideline
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Who should read this document?

Clinical staff in the renal directorate
Pharmacy staff

Key Messages

These guidelines are designed to provide members of the multi-disciplinary team with a summary of evidence based clinical practice guidelines related to the management of CKD-MBD. It supports a uniform approach to the management of this condition while allowing individualisation as required. Treatment should take into account patients' needs and preferences and should be culturally appropriate. Where there is no clear guidance or evidence to direct the choice of product a decision is made taking into account: efficacy, side effects, patient factors and cost. The Renal Association guidelines and each algorithm in this guideline can be used separately or in conjunction with each other.

Background & Scope

Normal calcium and phosphate metabolism

In patients with normal kidney function, the parathyroid gland regulates the serum calcium level in a number of ways. If the serum calcium level drops, calcium sensing receptors on the surface of the parathyroid gland detect this and the parathyroid gland consequently releases more parathyroid hormone (PTH). PTH acts to return the serum calcium level to normal in the following ways:

- Calcium and phosphate release from bone
- Increased renal tubular reabsorption of calcium and reduced phosphate reabsorption
- Increased 1-alpha-hydroxylase activity with subsequent increased calcitriol production and increased calcium and phosphate absorption from the gastrointestinal tract.

Calcium and Phosphate metabolism in CKD:

Phosphate

As the kidney function deteriorates the ability of the kidney to excrete phosphate diminishes. In early kidney disease (CKD stages 1-3) high serum phosphate may not be seen due to compensatory mechanisms such as increased uptake in bone or reduced renal tubular reabsorption. In later stages of kidney disease (CKD stage 4-5) hyperphosphataemia is an inevitable occurrence.

Hyperphosphataemia can have serious consequences and has been associated with an increased mortality amongst dialysis patients. Hyperphosphataemia is also implicated in the development of secondary hyperparathyroidism, cardiovascular and soft tissue calcification and calciphylaxis.

Calcium
In patients with kidney disease the ability of the kidney to synthesize 1-alphahydroxylase is diminished, tubular reabsorption of calcium and phosphate is impaired as is the skeletal “buffer”. These effects culminate in a low serum calcium level which stimulates PTH secretion from the parathyroid gland.

Parathyroid hormone (PTH)
PTH is not able to completely correct serum calcium due to impaired compensatory mechanisms so PTH secretion increases again which leads to secondary hyperparathyroidism. If secondary hyperparathyroidism is not treated effectively the parathyroid gland may develop hyperplastic nodules which secrete PTH irrespective of any negative feedback, this is termed tertiary hyperparathyroidism and requires parathyroidectomy.

Calcium and phosphate targets
Standards for serum calcium, phosphate and PTH referred to in this guideline are based on the current Renal Association and KDIGO guidelines (1, 2). Doses of phosphate binders and alfacalcidol should be adjusted to maintain serum levels within the reference ranges shown below. Consider trends (e.g. 3 consecutive serum levels) rather than ‘one off’ results. Rapidly rising PTH levels, even if within the normal range, warrant more aggressive monitoring and management.

What is new in this version?

Addition of Velphoro as third line option, information for primary care professionals.

Guideline

Prescribing of medicines for the management of chronic kidney disease – mineral bone disorder (CKD-MBD).

The Greater Manchester Medicines Management Group, Interface prescribing subgroup issues an approved formulary for medicines across Greater Manchester in addition to a Red-Amber-Green list of medicines. This framework defines where clinical and prescribing responsibility lie by categorising individual medicines. Note this is not a rigid guideline and is an advisory list.

Most medicines used in the management of CKD-MBD are appropriate for prescribing in primary care, following specialist initiation. The responsible commissioner is the relevant CCG

Drug	Status	
Alfacalcidol	Green following specialist advice	May be prescribed in primary care following written or verbal advice from a specialist and can then be subsequently prescribed in primary care with little or no additional monitoring required
Aluminium hydroxide	Green following specialist initiation	Specialist initiation, transfer of prescribing should occur after initiation and an initial review in secondary care
Calcichew™ 500mg chewable tablets		

Osvaren™ Calcium acetate (Phosex™ / Phoslo™)		
Lanthanum Sevelamer	Green following specialist initiation	Specialist initiation, transfer of prescribing should occur after initiation and an initial review in secondary care. Note that although these medicines are currently commissioned by NHS England prescribing has not been repatriated to secondary care and prescribing should be undertaken in primary care. They are exempt from the Drug Tariff and prescribing in primary care is the best option for patients.
Sucroferric oxyhydroxide (Velphoro ™) Cinacalcet	Red – Hospital only	Must be prescribed, dispensed and monitored by secondary care. The responsible commissioner is the NHS England specialist commissioning team.

CKD STAGE 3-4
eGFR 15 – 59ml/min/1.73m^2

Biochemistry reference range		Routine test schedule
PO4	Suggest within normal range (E)[2]	[a]3 – 6 months or on attendance if less frequent
CCa	Maintain within normal reference range[1,2] (E)[2]	[a]3 – 6 months or on attendance if less frequent
PTH	Optimal range unknown[1] Suggest within normal range (GP)[2]	[a]6 – 12 months or on attendance if less frequent
25-OH Vit D* (D2 + D3)	Maintain as per general population (E)[2] Refer to GMMMG guidelines	[b]If PTH elevated
HCO3 (total CO2)	Normal reference range[2]	Monthly or on attendance if less frequent
ALP	Normal reference range	[c]12 months

E = Evidence GP = Good Practice O = Opinion

[a]Frequency is determined by presence and magnitude of abnormalities and rate of CKD progression, therefore frequency may be increased at discretion of medical team[2]
[b]Serum 25- hydroxyl vitamin D should be measured in all patients with elevated PTH[1] (E), <20ng/ml indicates vitamin D insufficiency (O)[2]. Frequency determined by baseline value and therapeutic interventions[1].
[c]More frequently in presence of elevated PTH, at discretion of medical team.

GUIDELINE FOR THE MANAGEMENT OF CHRONIC KIDNEY DISEASE, MINERAL AND BONE DISRDER (CKD-MBD)

CKD STAGE 5 non dialysis

eGFR <15 ml/min/1.73m^2

Biochemistry reference range		Routine test schedule
PO4	Suggest within normal range (E)[2]	[a]1-3months
CCa	Maintain within normal reference range[1,2] (E)	[a]1-3 months
PTH	Optimal range unknown[1] (GP)[2] If marked change in either direction within target range then this should prompt change in therapy to avoid progression outside of range	[a]3-6 months
25-OH Vit D	Maintain as per general population (E)[2] Refer to GMMMG guidelines	[b]If PTH elevated
HCO3	Normal reference range[2]	Monthly or on Attendance if less Frequent
ALP	Normal reference range	[c]12 months

E = Evidence GP = Good Practice O = Opinion

[a]Frequency is determined by presence and magnitude of abnormalities and rate of CKD progression, therefore frequency may be increased at discretion of medical team[2]
[b]Serum 25- hydroxyl vitamin D should be measured in all patients with elevated PTH[1] (E), <20ngl/ml indicates vitamin D insufficiency (O)[2]. Frequency determined by baseline value therapeutic interventions[1].
[c]More frequently in presence of elevated PTH, at discretion of medical team.

CKD STAGE 5 *dialysis*

eGFR <15 ml/min/1.73m2

Biochemistry reference range		Routine test schedule
Phosphate	Within normal reference range for the unit	1-3months
Corrected Calcium	Within normal reference range for the unit	1-3months
PTH	Optimal range unknown Suggest 2-9 x upper end of normal reference range Marked change in either direction within reference range should prompt change in therapy to avoid progression outside range.	Every three months
Bicarbonate	Within normal reference range for the unit	1-3months
Alkaline Phosphatase	Within normal reference range for the unit	Every three months

E = Evidence GP = Good Practice O = Opinion

* Low PO4 levels < 1.13mmol/l are associated with increased risk of death[1]. Ensure sample has not been taken within 1 hour of dialysis. Low PO4 levels may indicate malnutrition. Consider stopping phosphate binders and referral to dietetics. Some patients may require phosphate supplementation.
[a]Frequency is determined by presence and magnitude of abnormalities, therefore frequency may be increased at discretion of medical team.
[b] Frequency is determined by presence and magnitude of abnormalities, post parathyroidectomy, dose titration of vitamin D and/or calcimimetic, therefore frequency may be increased at discretion of medical team or according to departmental guideline.

Dialysis adequacy and compliance

Phosphate is not easily removed by dialysis as it is largely an intracellular ion. However, if dialysis adequacy is consistently poor then this may contribute to hyperphosphataemia. Optimising dialysis adequacy or converting to daily dialysis or to haemodiafiltration may improve phosphate removal.

Compliance with phosphate binders is often poor due to the high tablet burden, large tablet size and side effects. Phosphate binders must be taken at meal times but may reduce the appeal of food. The pharmacist may be able to help with providing information on different formulations available, counselling patients and providing reminder charts / compliance aids where appropriate.

Dietetic referral

A referral to the Renal Dietitian is recommended to ensure that a reduced dietary phosphate intake is achieved whilst still maintaining overall nutritional adequacy of the diet and advice can be given in relation to checking labels for phosphate additives.

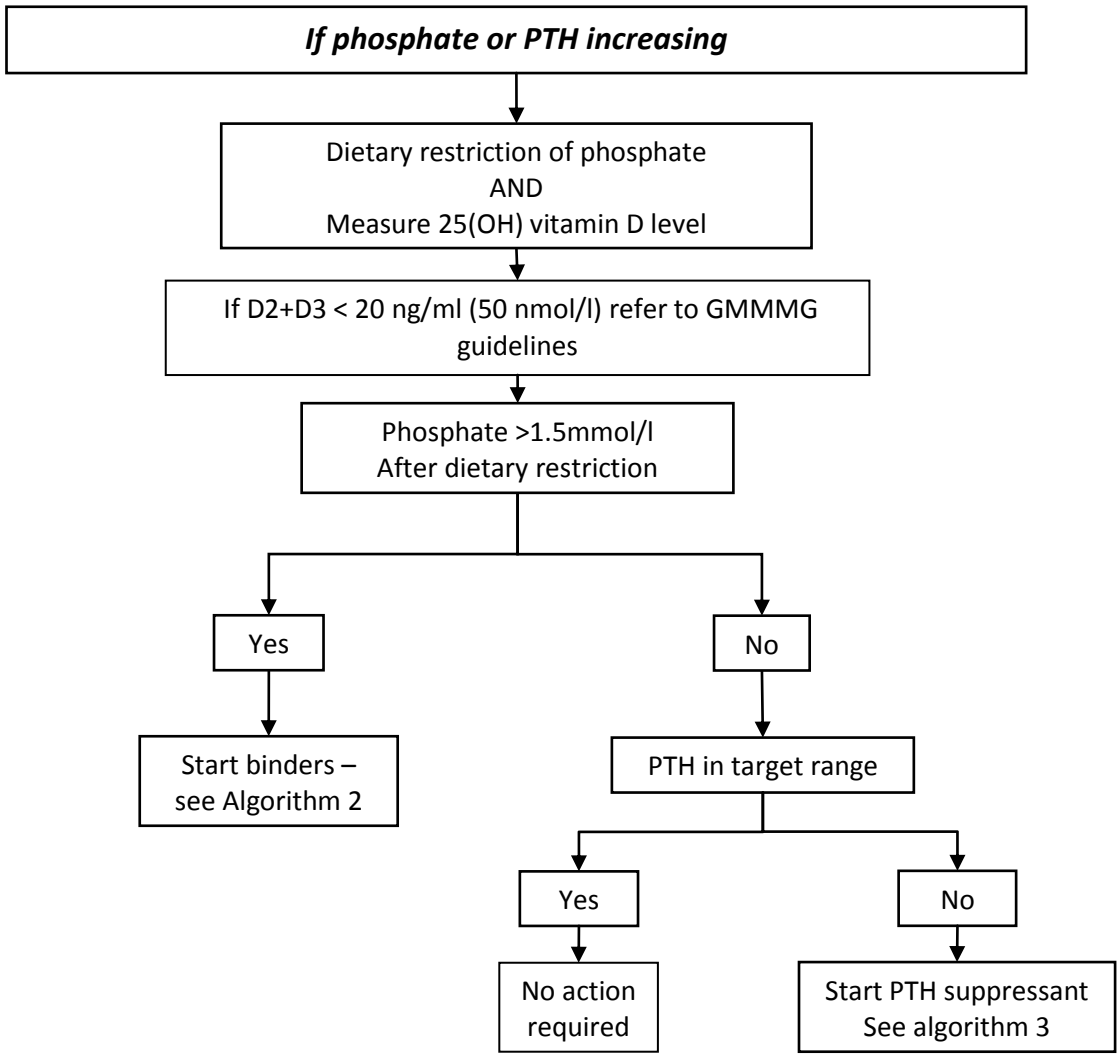
The Renal Dietitian can provide patients with written information to advise them on how to reduce the overall phosphate content of their diet.

The main dietary sources of phosphate are:

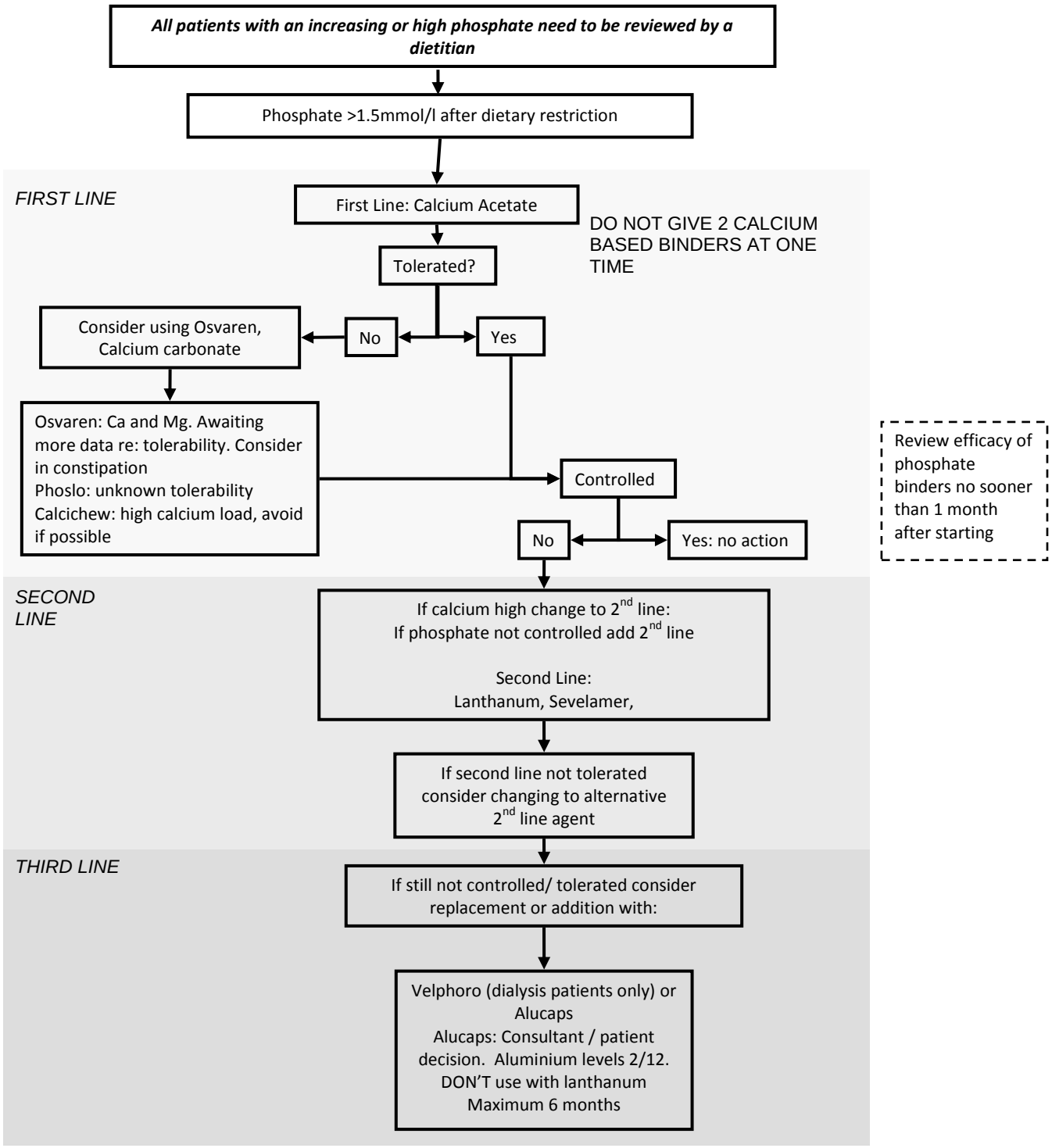
- **Dairy produce**
  Foods that contain protein such as milk, cheese, yoghurt and eggs are the richest source of phosphate. Achieving a low dietary phosphate intake should not compromise overall nutritional status.

- **Phosphate additives**
  Manufacturers are increasingly adding phosphate in the form of phosphate additives to lots of different foods. Nearly half of our daily phosphate intake comes from phosphate additives and almost all of this is absorbed by the body. Phosphate additives therefore can have more effect on the levels in blood than that from natural sources.

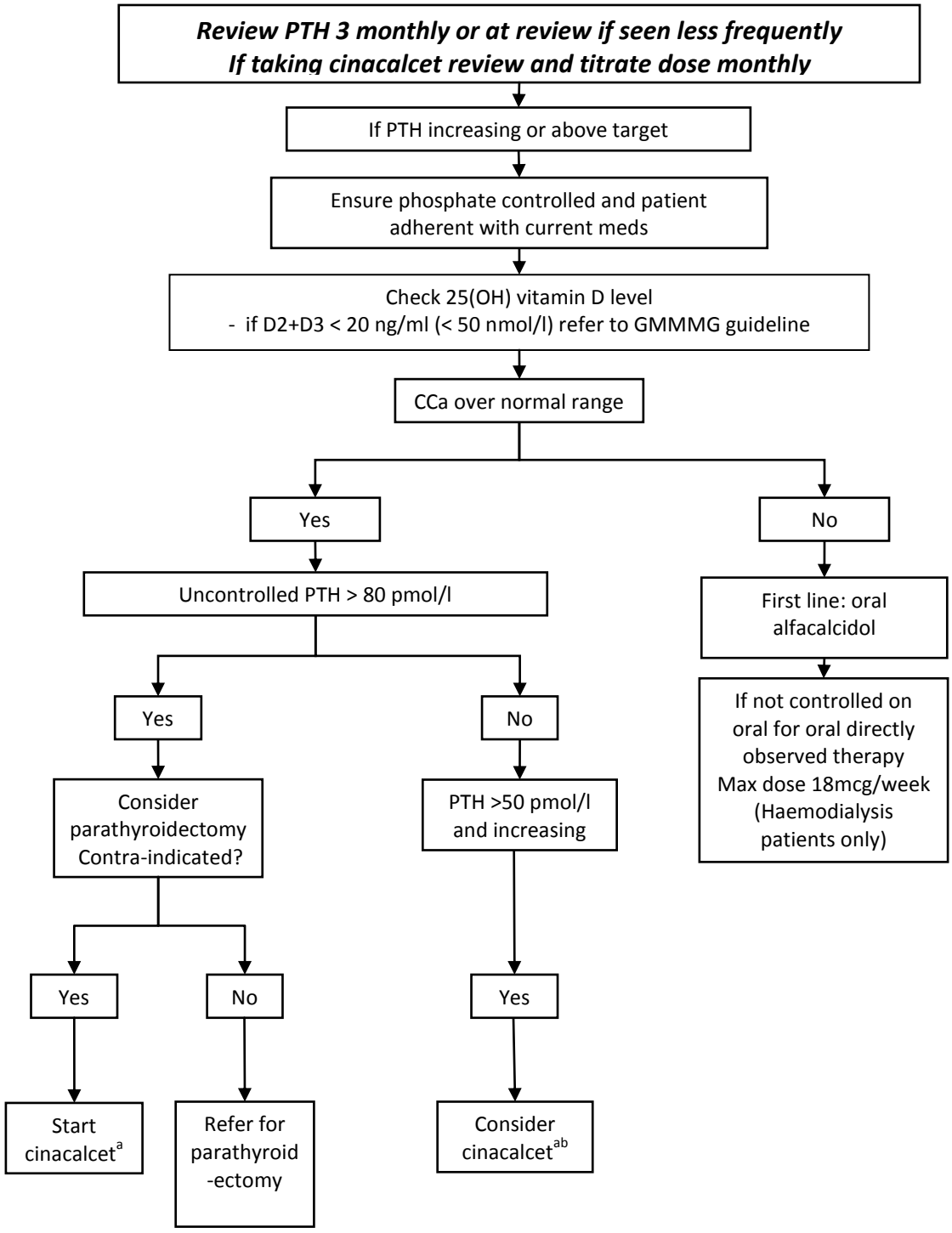
ALGORITHM 1: OVERVIEW OF MANAGEMENT: all renal patients



ALGORITHM 2: PHOSPHATE MANAGEMENT

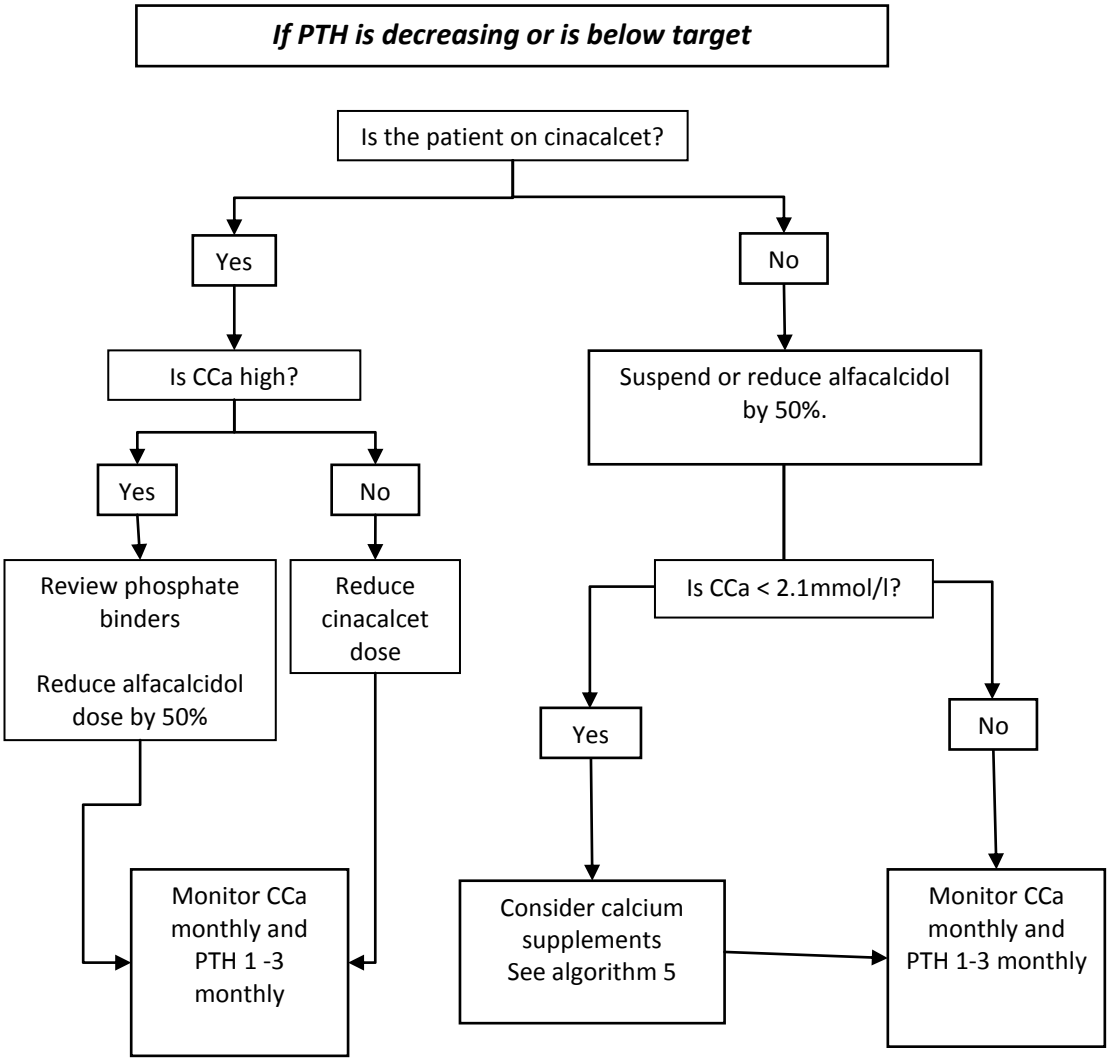


ALGORITHM 3: MANAGEMENT OF INCREASING PTH OR A PTH ABOVE TARGET RANGE IN ALL RENAL PATIENTS

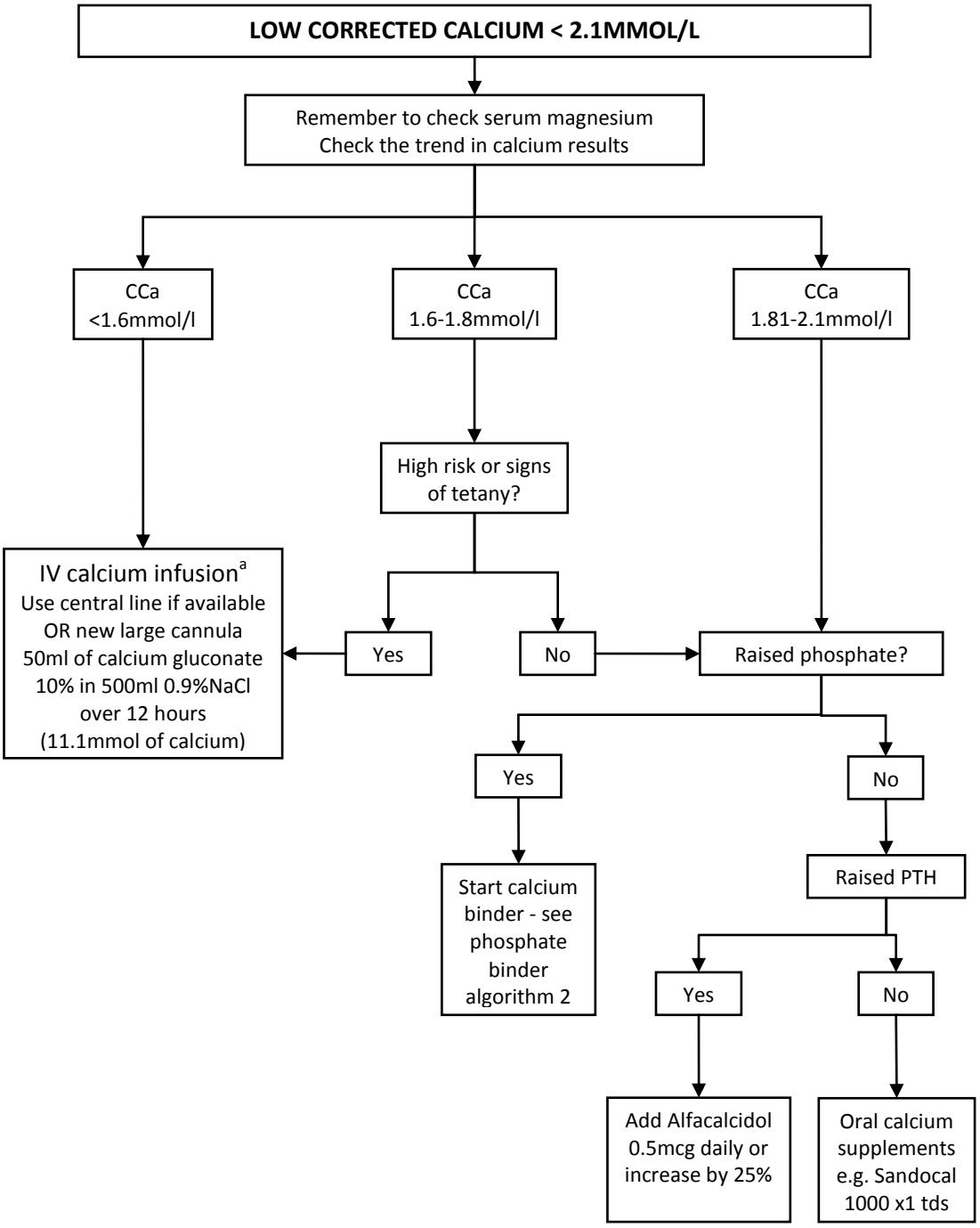


[a]Note: Cinacalcet NOT licensed in CKD or Transplant
[b]Note: Outside of NICE guidance
PTH assays taken from different hospitals are NOT interchangeable
For further details see rationale on page 16

ALGORITHM 4: MANAGEMENT OF DECREASING PTH OR PTH BELOW TARGET IN ALL RENAL PATIENTS



ALGORITHM 5: MANAGEMENT OF LOW CORRECTED CALCIUM



[a] Calcium gluconate is highly irritant and should be used with caution. If peripheral administration, use a large gauge cannula in a large vein and check the infusion site every 15 minutes to ensure extravasation injury has not occurred.

Rationale: Overall management

- Phosphate should always be controlled first prior to prescribing PTH suppressant medicines
- Renal Association guidelines suggest 25(OH) vitamin D levels should be checked in all non-dialysis patients whose PTH is increasing
- There is only association data to suggest it would be beneficial to offer D3 replacement in dialysis patients who are 25(OH) deficient

Rationale: Phosphate Management

- 1st line phosphate binder is to be a calcium based phosphate binder – preferably Phosex ®
- Phosex® is licensed, has a low cost and is efficacious.
- PhosLo® is a capsule and may be better tolerated than the tablet Phosex®. It is a similar price and is cheaper than 2nd line agents
- Osvaren contains low dose calcium and magnesium. It may be beneficial in patients with constipation.
- Calcichew contains a high dose of calcium. There is some evidence that calcium load may accelerate vascular calcification so high doses should be avoided where possible
- Second and third line agents may be added to first and second line agents respectively to enable a lower dose to be given. This will reduce cost and potentially improve tolerability by avoiding high doses.
- Ensure that patients take phosphate binders immediately before food EXCEPT LANTHANUM which is taken AFTER food.
- Sucroferric oxyhydroxide (Velphoro) and Alucaps are available as third line options. If using Alucaps measure aluminium levels every 2 months.

Rationale: PTH suppressant medication

- There is no evidence to suggest increased efficacy with intravenous (IV) versus oral alfacalcidol, however there is a substantial increase in cost.

- NOTE: Cinacalcet is not licensed in CKD or transplant patients and can cause severe hypocalcaemia. Close monitoring of calcium is essential when prescribing cinacalcet, especially if prescribing outside of the marketing authorisation. All patients on cinacalcet need to have PTH reviewed every month and medications adjusted accordingly (see algorithm 3).
- The efficacy of cinacalcet must be reviewed 6 months after starting treatment. Cinacalcet must be stopped if there has not been a 30% reduction of PTH by 6 months.[a]

Rationale: PTH decreasing or below target

- A low PTH is associated with an increased risk of adynamic bone disorder. This has been associated with an increased risk of vascular calcification
- Alfacalcidol can increase calcium so it is important to monitor calcium levels if the alfacalcidol dose is reduced.

Rationale: 25(OH) vitamin D replacement and maintenance

- Low 25(OH) vitamin D levels have been associated with an increased risk of infection, malignancy, hypertension and diabetes
- It occurs due to a deficiency of D3 and D2, not due to liver impairment
- 85% of 25(OH) vitamin D is used intracellular for autocrine and paracrine functions – these functions are not affected by 1 alfacalcidol
- 25(OH) vitamin D deficiency needs replacement even if taking alfacalcidol
- Please ensure patient only takes replacement dose for a maximum of 10 days to prevent hypercalcaemia
- Please ensure Greater Manchester Medicines Management Group guidelines are used: http://gmmmg.nhs.uk/docs/nts/NTS%20Vit%20D%20for%20Insufficiency%20&%20Deficiency.pdf

Rationale: Management of low corrected calcium (see algorithm 5)

- Hypocalcaemia can be life threatening
- If giving IV calcium ensure a large vein is used as severe skin necrosis can occur
- Avoid using phosphate binders as calcium supplements to ensure clarity for patients and enable tablets to be taken correctly
- Sando-cal 1000 or Calcium 500 tablets should be first-line calcium supplements and should be taken 2 hours before or after food

Rationale: Transplant patients

- Transplant patients should follow CKD 5 protocol and guidance
- Note cinacalcet is not licensed in transplant patients as can cause severe hypocalcaemia. If used close monitoring of calcium is essential
- There is little evidence for targets in transplant patients; they are based on opinion.

[a] NICE recommends review of cinacalcet efficacy at 3 months. KDIGO guidelines recommend monitoring trends in biochemical parameters to guide treatment of CKD-MBD. We therefore recommend review of cinacalcet at 6 months.

Standards

The Renal Association/ Registry standards should be adhered to for CKD 5 patients receiving Renal Replacement Therapy with dialysis.

Information for Primary Care Professionals

The purpose of this information is to provide general practitioners an overview of the phosphate binders currently used by renal multidisciplinary teams across Greater Manchester. This document has been compiled in response to requests for information and is not intended to change the current responsibilities of the prescriber.

Phosphate Management

Hyperphosphataemia is an inevitable consequence of renal failure occurring in many pre-dialysis and most dialysis patients. Hyperphosphataemia has been associated with an increased mortality amongst dialysis patients and is implicated in the development of secondary hyperparathyroidism, cardiovascular and soft tissue calcification and calciphylaxis.

Doses of phosphate binders are adjusted to maintain serum phosphate and corrected calcium within current British Renal Association Standards. Patients should take phosphate binders immediately before food except lanthanum which is taken after food.

Gastrointestinal side effects to phosphate binders are common including nausea, vomiting, abdominal pain, constipation, diarrhoea dyspepsia, flatulence.

Binders can reduce the absorption of quinolones (e.g. ciprofloxacin) and tetracyclines (e.g. doxycycline) and iron preparations administration should be at least 2 hours before or after these medicines. In severe infections consider withholding binders until the antibiotic course has been completed.

Additionally ciclosporin and mycophenolate absorption may be reduced by sevelamer administration and should be administered at least 2 hours before or after the above medicines. Iron absorption is not affected by sevelamer administration.

Lanthanum increases the gastric pH so should not be administered within 2 hours before or after administration of medicines known to interact with antacids e.g. chloroquine, ketoconazole, hydroxychloroquine.

<u>Rationale for choosing phosphate binders</u>

Phosphate binders used can be split into two groups:

- <u>Calcium containing binders</u>: These are usually used when a patient has a normal serum calcium or requires calcium supplements to maintain serum calcium levels. The preparation used depends on tolerability. Calcium based binders remain first line as they are both cheap and effective.
    - Calcium acetate: contains less calcium and is used when using calcium carbonate is likely to cause high serum calcium levels.
        - Phosex® is licensed, has a low cost and is efficacious.

- PhosLo® is a similar price and may be better tolerated due to being in capsule form.
- Calcium carbonate (Calcichew, Adcal, Calcium 500) contains more calcium and is usually reserved for patients with low calcium levels due to concerns that calcium load may accelerate vascular calcification. High doses should be avoided where possible.
- Osvaren® contains low dose calcium and magnesium and may be beneficial in patients with constipation.

- Non-calcium containing binders: These are second line and are usually used when serum calcium levels are high or where there is evidence of vascular calcification. These agents should be added to first line agents where possible to enable a lower dose to be given. This will reduce cost and potentially improve tolerability by avoiding high doses.
  - Sevelamer carbonate: a non-calcium non-aluminium based binder. Sevelamer is added into a binder regimen when calcium acetate is inadequate but may be used alone where there is evidence of vascular calcification. Sevelamer use is limited by its low potency requiring patients to take large numbers of tablets with each meal.
  - Lanthanum carbonate a has a greater potency than sevelamer and is can reduce the tablet burden for patients.
  - Sucroferric oxyhydroxide (Velphoro) is a new third line agent which may be more convenient to take for some patients due to the lower tablet burden (3 tablets per day) but is associated with more gastrointestinal side effects.
  - Aluminium hydroxide (Alu-caps®) remains the most cost-effective phosphate binder but concerns about safety mean that it is now rarely used other than for short 'rescue' courses. If using Alucaps for longer periods aluminium levels should be checked every 2 months.

GMMMG Formulary summary information:

Drug	Form	How taken	Starting dose	Max. daily dose	Status	Notes
Vitamin D						
Alfacalcidol	0.25 MICROgram 0.5 MICROgram 1 MICROgram 0.2mcg/ml drops (1drop = 1mcg)	Capsule / drops	0.25mcg three times a week	10 mcg daily	**Green** following specialist advice	May be prescribed in primary care following advice from a specialist then subsequently prescribed in primary care with little or no additional monitoring required Take care when prescribing as high-doses often pulsed 2-3x/week to avoid hypocalcaemia.
Colecalciferol	20,000 unit capsules	capsule	See GMMMG protocol		**Green** (Not assessed)	
Phosphate binding agents						
Phosex® (calcium acetate)	1g tablet	Swallowed whole	1 per meal	6 tablets	**Green**	
Phoslo® (calcium acetate)	667mg capsules	Swallowed whole	2 per meal	12 tablets		
Calcichew® (calcium carbonate)	500mg tablet	Chewable	1 per meal	3 tablets		
Calcium 500 (calcium carbonate)	500mg tablet	Swallowed whole	1 per meal	3 tablets		
Adcal® (calcium carbonate)	600mg tablet	Chewable	1 per meal	3 tablets		
Osvaren®	110mg calcium & 235mg magnesium	Swallowed whole	1 per meal	12 tablets		
Sevelamer carbonate	800mg tablets	Swallowed whole	6 tabs daily	12 tablets		Concomitant therapy with lanthanum not recommended
Lanthanum carbonate	500mg tablet 750mg tablet 1g tablets	chewable	2.25g daily	3g daily		Concomitant therapy with sevelamer not recommended
Sucroferric oxyhydroxide (Velphoro®)	500mg tablet	chewable	1500mg daily	3000mg daily	**Red**	Must be prescribed, dispensed and monitored by secondary care.
Alucaps®	475mg capsule	Swallowed whole or can be opened and mixed with food	4 capsules daily	12 capsules	**Green** (Not assessed)	
Hyperparathyroidism						
Cinacalcet	30mg 60mg 90mg	Tablet given after evening meal	30mg once daily	180mg daily	**Red**	Must be prescribed, dispensed and monitored by secondary care.

Explanation of terms & Definitions

Abbreviations

Al	Aluminium
ALP	Alkaline phosphatase
CCa	Corrected calcium
CKD	Chronic kidney disease
CKD-MBD	Chronic kidney disease - mineral bone disease
eGFR	estimated glomerular filtration rate
EPR	Electronic patient record
HCO3	Bicarbonate
MDT	Multi-disciplinary team
Mg	Magnesium
PO4	Phosphate
PTH	Parathyroid hormone (intact)
RPOW	Renal physician of the week

References and Supporting Documents

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5) Cinacalcet for the treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy. NICE technology appraisal guideline no 117, 2007 https://www.nice.org.uk/guidance/ta117
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8) Goodman WG. The consequences of uncontrolled secondary hyperparathyroidism and its treatment in chronic kidney disease. Seminars in Dialysis 2004 17 09-216
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Roles and responsibilities

Roles and Responsibilities of the Multi-professional Team

- Take a proactive approach in order to identify people with CKD-MBD and follow this guideline.
- Establish baseline biochemistry and monitor according to test schedule.
- Provide evidence based, best practice advice taking into account clinical circumstances, peoples needs and preferences. Use this to optimise understanding and compliance with diet modification, phosphate binders and relevant medications associated with the management of CKD-MBD.
- Initiate and review prescribing of phosphate binders, vitamin D, calcimimetics and titrate doses accordingly.
- Liaise with the patient and the GP regarding the prescribing and administration of phosphate binders, vitamin D and calcimimetics and facilitate patient education, understanding and adherence to diet and medications.
- Maintain effective communication between patients and healthcare professionals.
- Ensure distribution of information to local teams.
- Aim to meet 1-3 monthly for review depending on the patients' circumstances.

Document Control Information

Greater Manchester Guidelines on the Management of Chronic Kidney Disease - Mineral Bone Disorder	Salford Royal NHS NHS Foundation Trust University Teaching Trust safe • clean • personal Central Manchester University Hospitals NHS
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Classification: Clinical Guideline **Scope:** Renal Department. **Applies to:** Patients under the care of the renal team **Document for public display:** Yes	
Keywords: BONE, CALCIUM, PHOSPHATE, VITAMIN D, PARATHYROID HORMONE, PTH, CKD	
Associated Documents: • Medicines Policy.	
Unique Identifier: DDCRen2(12) **Issue number:** 2 **Replaces:** Issue 1 **Authorised by:** Medicines Management Exec Sub Group **Authorisation date:** **Next review:**	

Policy Implementation Plan

The guideline will be circulated to all medical and nursing staff in local renal teams, renal pharmacists and renal dietiticans.

The guidelines will be hosted on the GMMMG website to allow the access by GPs and CCGs Pharmacists.

The guideline will be included in the planned junior doctor teaching sessions both on induction and at the planned teaching sessions.

Monitoring and Review

NICE guidelines for phosphate binders and cinacalcet will be audited annually by a junior doctor nominated by the Renal Department audit lead. The findings will be reported to the North West Renal Audit and local audit and governance groups.

Adherence to standards for prescribing and clinical outcomes will be audited.
The automatic renal registry submission will also be reviewed locally and nationally to demonstrate achievement of national clinical standards for CKD MBD.

Endorsement

Endorsed by:		
Name of Lead Clinician/Manager or Committee Chair	**Position of Endorser or Name of Endorsing Committee**	**Date**

Screening Equality Analysis Outcomes

The Trust is required to ensure that all our policies/procedures meet the requirements of its service users, that it is accessible to all relevant groups and **furthers the aims of the Equality Duty for all protected groups by age, religion/ belief, race, disability, sex, sexual orientation, marital status/ civil partnership, pregnancy/ maternity, gender re-assignment. Due consideration may also be given to carers & socioeconomic factors.**

Have you been trained to carryout this assessment?
If 'no' contact Equality Team 62598 for details.

Name of policy or document : Greater Manchester Guidelines on the Management of Chronic Kidney Disease - Mineral Bone Disorder

Key aims/objectives of policy/document: These guidelines are designed to provide members of the multi-disciplinary team with a summary of evidence based clinical practice guidelines related to the management of CKD-MBD. It supports a uniform approach to the management of this condition while allowing individualisation as required. Treatment should take into account patients' needs and preferences and should be culturally appropriate. Where there is no clear guidance or evidence to direct the choice of product a decision is made taking into account: efficacy, side effects, patient factors and cost. The department will follow the Renal Association guidelines and each algorithm can be used separately or in conjunction with each other
(impact on both staff & service users)

1) a) Who is this document or policy aimed at?	Clinical staff caring for renal patients
2) a) Is there any evidence to suggest that your 'end users' have different <u>needs</u> in relation to this policy or document; (e.g. health/ employment inequality outcomes) (**NB If you do not have any evidence you should put in section 8 how you will start to review this data)**	no
3) a) Does the document require any decision to be made which could result in some individuals receiving different treatment, care, outcomes to other groups/individuals?	Decisions would be made on clinical grounds only
b) If yes, on what basis would this decision be made? **(It must be justified objectively)**	n/a
4) a) Have you included where you may need to make reasonable adjustments for disabled users or staff to ensure they receive the same outcomes to other groups ?	n/a

5) a) Have you undertaken any consultation/ involvement with service users or other groups in relation to this document?	n/a
b) If yes, what format did this take? Face/face or questionnaire? (please provide details of this)	
c) Have any amendments been made as a result?	
6) a) Are you aware of any complaints from service users in relation to this policy?	No
b) If yes, how was the issue resolved? Has this policy been amended as a result?	

7) a) To summarise; is there any evidence to indicate that any groups listed below receive different outcomes in relation to this document?

	Yes		No	unsure
	Positive	Negative*		
Age			X	
Disability			X	
Sex			X	
Race			X	
Religion & Belief			X	
Sexual orientation			X	
Pregnancy & Maternity			X	
Marital status/civil partnership			X	
Gender Reassignment			X	
Carers *1			X	
Socio/economic2**			X	

1: That these two categories are not classed as protected groups under thxe Equality Act.
2: Care must be taken when giving due consideration to socio/economic group that we do not inadvertently discriminate against groups with protected characteristics

Negative Impacts

*If any negative impacts have been identified you must either a) state below how you have eliminated these within the policy or b) conduct a full impact assessment:

8) How will the future outcomes of this policy be monitored? **During the planned audit as detailed in the guideline monitoring**

9) **If any negative impact has been highlighted by this assessment, you will need to undertake a full equality impact assessment:**

Will this policy require a full impact assessment? /No
(if yes please contact Equality Team, 62598/67204, for further guidance)

/Low Type/sign_ S Sinha/ E Lamerton
date: May 2016