NHS
National Institute for
Health and Clinical Excellence

Management of hyperphosphataemia

Costing report

Implementing NICE guidance

March 2013

NICE clinical guideline 157

Clinical Guideline Implementation Tools

This costing report accompanies the clinical guideline: 'Hyperphosphataemia in chronic kidney disease: management of hyperphosphataemia in patients with stage 4 or 5 chronic kidney disease' (available online at http://guidance.nice.org.uk/CG157).

Issue date: March 2013

The guidance is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting with healthcare professionals. It should be read in conjunction with the NICE guideline. The report and template are implementation tools and focus on the recommendations that were considered to have a significant impact on national resource utilisation.

The cost and activity assessments in the report are estimates based on a number of assumptions. They provide an indication of the likely impact and are not absolute figures. Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the template can be amended to reflect local practice.

Implementation of the guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.

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Executive summary

This costing report looks at the resource impact of implementing the NICE guideline 'Hyperphosphataemia in chronic kidney disease: management of hyperphosphataemia' in England, which applies to:

- adults, children and young people with stage 4 or 5 chronic kidney disease (CKD) who are not on dialysis and who are at risk of hyperphosphataemia **or**
- adults, children and young people with stage 5 CKD who are receiving haemodialysis or peritoneal dialysis and are at risk of hyperphosphataemia.

The costing method adopted is outlined in appendix A; it uses the most accurate data available, was produced in conjunction with key clinicians, and reviewed by clinical and financial professionals.

Potential resource-impact recommendations

This report focuses on the recommendations that are likely to have the greatest resource impact and therefore require the most additional resources to implement or can potentially generate the biggest savings. They are:

- A specialist renal dietitian should carry out a dietary assessment.
- For children and young people, offer a calcium-based phosphate binder as the first-line phosphate binder.
- For adults, offer calcium acetate as the first-line phosphate binder.

It is not possible to estimate with any degree of certainty the population that have CKD stages 4 and 5, and the proportion of these people that will currently be prescribed medication for the management of hyperphosphataemia. This is due to the wide variation in clinical practice and differences in clinical opinion. This report discusses the potential costs and savings that need to be considered at a local level.

However, implementation of the guideline is likely to reduce the number of people being prescribed sevelamer hydrochloride or lanthanum carbonate. The potential savings per person arising due to changes in prescribing are :

- Changing from sevelamer hydrochloride to either calcium carbonate or calcium acetate will result in annual savings of £2186 or £2096 per person respectively in adults.

- Changing from lanthanum carbonate to either calcium carbonate or calcium acetate will result in annual savings of £1806 or £1716 per person respectively in adults.

There are also likely to be costs associated with the increase in the number of people receiving a dietary assessment with a specialist renal dietitian. The cost of an assessment with a specialist renal dietitian is estimated to be £74.00 per person (see 3.1.5 for details).

Due to the small number of children who would be affected by this guidance, commissioners are advised to calculate costs on a case by case basis.

Commissioners are advised to check current practice in their local area and use the local costing template to ascertain the resource impact for their population.

Benefits and savings

Implementing the clinical guideline may result in the following savings and benefits:

- More effective dietary phosphate management in people with CKD stages 4 and 5.
- A decrease in the cost of drugs prescribed to adults as clinicians prescribe calcium acetate as the first-line phosphate binder.
- A decrease in the cost of drugs prescribed to children as clinicians prescribe calcium-based phosphate binders as the first-line phosphate binder.

- A reduction in complications arising from high serum phosphate levels, for example secondary hyperparathyroidism, if people are adherent to diet and medication.
- Improved access to a dietitian for people with hyperphosphataemia.

Local costing template

A local costing template has been produced to support this guideline which enables organisations in England, Wales and Northern Ireland to estimate the impact locally and replace variables with ones that depict the current local position.

1 Introduction

1.1 Supporting implementation

1.1.1 The NICE clinical guideline on the management of hyperphosphataemia is supported by the following implementation tools available on our website http://guidance.nice.org.uk/CG157:

- Costing tools
  - a costing report; this document
  - a local costing template; a spreadsheet that can be used to estimate the local cost of implementation.
- Two educational slide sets (1 for adult services and 1 for children and young people's services); key messages for local discussion.
- Two clinical case scenarios (1 for adult services and 1 for children and young people's services); example cases designed to improve and assess the users' knowledge of the guidance.
- Two clinical audit tools (1 for adult services and 1 for children and young people's services); measure current practice against the guidance and identify areas in which practice can be improved.

1.2 What is the aim of this report?

1.2.1 This report aims to help organisations plan for the financial implications of implementing NICE guidance.

1.2.2 This report does not reproduce the NICE guideline on the management of hyperphosphataemia and should be read in conjunction with it (see www.nice.org.uk/guidance/CG157).

1.2.3 The costing template that accompanies this report is designed to help those assessing the resource impact at a local level in England, Wales or Northern Ireland.

1.3 Epidemiology of hyperphosphataemia

1.3.1 CKD describes abnormal kidney function and/or structure.

1.3.2 The 'National service framework for renal services' adopted the US 'National Kidney Foundation kidney disease outcomes quality initiative' (NKF-KDOQI) classification of CKD. This classification divides CKD into 5 stages according to the extent of a person's loss of renal function. Stage 4 CKD is defined by a glomerular filtration rate (GFR) of 15–29 ml/min/1.73 m^2, and stage 5 by a GFR of less than 15 ml/min/1.73 m^2. (A GFR of over 90 ml/min/1.73 m^2 is considered normal unless there is other evidence of kidney disease.)

1.3.3 CKD progresses to these more advanced stages in a small, but significant percentage of people. In 2010, the Health Survey for England reported a prevalence of moderate to severe CKD (stages 3 to 5) of 6% in men and 7% in women. CKD stages 4 and 5 were reported at a prevalence of 1% or less. This equates to approximately 520,000 people in England.

1.3.4 As kidney dysfunction advances, some comorbidities become more severe. Hyperphosphataemia is an example of this, and occurs because of the insufficient filtering of phosphate from the blood by poorly functioning kidneys. The result is that a certain amount of the phosphate does not the leave the body in the urine, instead remaining in the blood at abnormally elevated levels.

1.3.5 There are recommended levels at which serum phosphate should be maintained, with different levels for adults and children and young people. For adults, there are different levels for people who are on dialysis and those who are not.

1.3.6 Data from the UK Renal Registry 2011 showed that 56% of patients receiving haemodialysis and 69% of patients receiving

peritoneal dialysis achieved serum phosphate levels within the recommended range.

1.3.7 An ageing population, together with an increasing incidence of diabetes and better survival, means that the number of patients needing dialysis and adequate phosphate management is increasing. Between 2005 and 2009, the number of patients needing dialysis increased at a rate of 3.5% per year.

1.4 Current service provision

1.4.1 For adults with stage 4 or 5 CKD who are not on dialysis, the UK Renal Association guidelines recommend that serum phosphate levels be maintained at between 0.9 and 1.5 mmol/l. For adults with stage 5 CKD who are on dialysis, it is recommended that serum phosphate levels be maintained at between 1.1 and 1.7 mmol/l.

1.4.2 For children and young people with stage 4 CKD, the NKF-KDOQI recommends that serum phosphate levels be maintained within age-appropriate limits. For those with stage 5 CKD, including those on dialysis, it is recommended that serum phosphate levels be maintained between 1.3 and 1.9 mmol/l for those aged 1–12 years, and between 1.1 and 1.8 mmol/l during adolescence.

1.4.3 There is wide variation in the management of serum phosphate levels between renal centres in the UK. This, together with a rising prevalence of CKD led to the development of the NICE clinical guideline on the management of hyperphosphataemia.

1.4.4 Analysis of prescribing data from the EPACT system shows an annual spend on drugs to manage hyperphosphataemia of approximately £11 million per annum in primary care. However, some drugs may also be prescribed in secondary care.

2 Costing methodology

2.1 Process

2.1.1 We use a structured approach for costing clinical guidelines (see appendix A).

2.1.2 We have to make assumptions in the costing model. These are tested for reasonableness with members of the Guideline Development Group (GDG) and key clinical practitioners in the NHS.

2.2 Scope of the cost-impact analysis

2.2.1 The guideline offers best practice advice on the 'management of hyperphosphataemia in patients with stage 4 or 5 chronic kidney disease' in England.

2.2.2 The guidance does not cover adults, children and young people with stage 1–3 kidney disease. Therefore, these issues are outside the scope of the costing work. Further clarity on the scope of this guidance can be obtained from the full guideline.

2.2.3 We worked with the GDG and other professionals to identify the recommendations that would have the most significant resource-impact (see table 1). Costing work has focused on these recommendations.

Table 1 Recommendations with a significant resource impact

Recommendation	Recommendation number
A specialist renal dietitian, supported by healthcare professionals with the necessary skills and competencies, should carry out a dietary assessment and give individualised information and advice on dietary phosphate management.	1.1.1
For children and young people, offer a calcium-based phosphate binder as the first-line phosphate binder to control serum phosphate in addition to dietary management.	1.1.5
For adults, offer calcium acetate as the first-line phosphate binder to control serum phosphate in addition to dietary management.	1.1.8

2.2.4 Three of the recommendations in the guideline are considered to have a significant resource impact.

2.2.5 We have limited the consideration of costs and savings to direct costs to the NHS that will arise from implementation. We have not included consequences for the individual, the private sector or the not-for-profit sector. If applicable, any realisable cost savings arising from a change in practice have been offset against the cost of implementing the change.

2.3 General assumptions made

2.3.1 Estimates of the prevalence of CKD stages 4 and 5 vary between 0.5% and 1.0%.

2.4 Basis of unit costs

2.4.1 If a national tariff price or indicative price exists for an activity, this has been used as the unit cost.

2.4.2 Using these prices ensures that the costs in the report are the cost to the commissioning organisation of commissioning predicted changes in activity at the tariff price, but it may not represent the actual cost to individual trusts of delivering the activity.

3 Significant resource-impact recommendations

3.1 Dietary management: children, young people and adults

Recommendation

A specialist renal dietitian, supported by healthcare professionals with the necessary skills and competencies, should carry out a dietary assessment and give individualised information and advice on dietary phosphate management.

Background

3.1.1 Standard management of hyperphosphataemia involves the use of both pharmacological and non-pharmacological interventions, as well as the provision of education and support. However, there is wide variation between renal centres in the UK in how these interventions are used.

3.1.2 Although there was no evidence on the effectiveness of a low-phosphate diet without protein restriction (for example, exchanging foods with a high phosphate to protein ratio for foods with a low phosphate to protein ratio), there was consensus among the GDG that this has been effective in their own clinical experience. The GDG considered that advising patients to reduce their intake of phosphate-rich foods is good clinical practice. The GDG also felt that the same principle could be extended to the nutritional supplements and substitutes currently used in CKD management to maintain protein intake, giving low-phosphate options where possible.

In children, the GDG felt that malnutrition is of much greater concern than hyperphosphataemia. Progressive CKD is often associated with decreased spontaneous dietary protein intake, which is a priority for treatment given the need to maintain growth and adequate nutritional status. For these reasons, as well as the lack of paediatric evidence available, the GDG could not recommend a diet based on protein restriction for children. Recommended intakes are instead age-specific according to reference nutrient intakes.

Assumptions made

3.1.3 Expert opinion suggests that 95%-100% of children with CKD stages 4 and 5 currently receive a dietary assessment carried out by a specialist renal dietitian. For the purposes of the costing model we have assumed that all children with CKD stages 4 and 5 currently receive a dietary assessment. Where local

circumstances vary, the costing template can be amended to reflect this.

3.1.4 The proportion of adults who currently receive a dietary assessment by a specialist renal dietitian varies widely, but expert opinion suggests that it is approximately 75%.

3.1.5 The cost of a dietary assessment by a specialist renal dietitian is based on the cost of a non-consultant led first attendance non-admitted face-to-face appointment –Dietetics; £74.00 from the National schedule of reference costs NHS Trusts and Foundation Trusts 2011–12.

3.1.6 It has been assumed that there will always be a small percentage of adults who will not receive a dietary assessment by a specialist renal dietitian, so the future proportion of people who will be assessed has been estimated to be 95%.

Potential costs

3.1.7 The estimated cost of increasing the proportion of adults who receive a dietary assessment by a specialist renal dietitian is £74.00 per person.

Other considerations

3.1.8 The GDG envisaged that, while the initial dietary assessment would be undertaken by a specialist renal dietitian, this advice would be reiterated by all healthcare professionals at every patient contact. Expert opinion suggests that the healthcare professionals who would be involved in the care of people with CKD stages 4 and 5, such as specialist and renal trained nurses, and assistant practitioners, have sufficient expertise to reiterate advice, check compliance and advise further. They would also be able to identify when a dietitian needs to review the advice. However, dietetic teaching would be needed for new and less experienced staff, along with ‘refresher courses’ for existing staff.

This is likely to take the form of updates every 1–3 years as needed.

3.1.9 It is the opinion of the GDG that dietary advice is the first-line treatment for the management of hyperphosphataemia, not pharmacological interventions.

3.2 Phosphate binders: children and young people

Recommendation

For children and young people, offer a calcium-based phosphate binder as the first-line phosphate binder to control serum phosphate in addition to dietary management.

Background

3.2.1 Early intervention to prevent or manage high phosphate levels was considered key to preventing downstream complications resulting from the poor management of serum calcium and parathyroid hormone levels. The GDG therefore emphasised the importance of starting phosphate binder therapy early, and stressed that this should be in the context of concurrent dietary management of serum phosphate.

3.2.2 Although no evidence was found concerning the effectiveness of phosphate binders in children, the GDG felt that a calcium-based binder would be desirable as the first-line phosphate binder used in children. This is because children need additional calcium for their growing bones, but also to avoid the effects of secondary hyperparathyroidism that can arise in young patients with chronically low serum calcium levels. However, the GDG did not feel there was sufficient evidence to distinguish between the use of calcium acetate and calcium carbonate in children. Therefore, they felt it appropriate to leave the choice between the 2 calcium-based binders to be made on a case-by-case basis, taking into

account patient preference, the ease of administration and the specific clinical circumstances.

Assumptions made

3.2.3 Due to the small number of children who would be affected by this guidance, commissioners are advised to calculate costs on a case by case basis.

Other considerations

3.2.4 Expert opinion suggests that most of the children and young people are already being prescribed calcium-based phosphate binders as the first-line phosphate binder.

3.2.5 There is wide variation in the use of calcium- and non-calcium-based phosphate binders. As a result, it is difficult to predict the degree to which prescribing practice might change after implementation of the guideline. Organisations are advised to check prescribing practice in their area to estimate the impact of implementing the guidance locally.

3.3 Phosphate binders: adults

Recommendation

For adults, offer calcium acetate as the first-line phosphate binder to control serum phosphate in addition to dietary management.

Background

3.3.1 Early intervention to prevent or manage high phosphate levels was considered key to preventing downstream complications resulting from the poor management of serum calcium and parathyroid hormone levels. The GDG therefore emphasised the importance of starting phosphate binder therapy early, and stressed that this should be in the context of concurrent dietary management of serum phosphate.

Assumptions made

3.3.2 The cost of the drugs used to control serum phosphate was based on the health economic analysis for the guideline. NICE Clinical guideline 157 – management of Hyperphosphataemia, Appendix F - Health economic analysis, Table 14. These costs were updated to the cost per the Electronic Drug Tariff –accessed February 2013.

3.3.3 The average dose used was the dose at which each binder was delivered to achieve the clinical effect observed in the evidence base. The average daily doses used are:

- calcium carbonate 3.66 g/day
- calcium acetate 4.82 g/day
- sevelamer hydrochloride 6.37 g/day
- lanthanum carbonate 1.93 g/day.

3.3.4 Expert opinion suggests that sevelamer carbonate is currently prescribed in a small number of cases, although it is not recommended by the guideline. Thus, implementing the guidance may result in a reduction in the prescribing levels of sevelamer carbonate in future. As the cost of sevelamer carbonate is similar to sevelamer hydrochloride, it has been assumed that any cost impact as a result of any reduction in prescribing would be included in the changes in the cost of prescribing sevelamer hydrochloride. Where prices change due to the availability of generic drugs the costing template can be updated to reflect this.

Potential savings

3.3.5 The estimated savings achievable from using calcium acetate as the first-line phosphate binder in adults per person are :

- Changing from sevelamer hydrochloride to either calcium carbonate or calcium acetate will result in savings of £2186 or £2096 per person respectively.

- Changing from lanthanum carbonate to either calcium carbonate or calcium acetate will result in savings of £1806 or £1716 per person respectively.

Other considerations

3.3.6 Expert opinion suggests that non-calcium-based binders make up between 30% and 60% of current first line prescribing for adults. The midpoint of 45% has been used, split equally between the 2 non-calcium-based binders.

3.3.7 It has been estimated that that 35%-40% of adults are currently being prescribed calcium acetate.

3.3.8 There is wide variation in the use of calcium- and non-calcium-based phosphate binders. As a result, it is difficult to predict the degree to which prescribing practice might change after implementation of the guideline. Organisations are advised to check prescribing practice in their area to estimate the impact of implementing the guidance locally.

3.4 Benefits and savings

The benefits and savings that may be achieved as a result of implementing this guidance have all been covered in section 3.

4 Impact of guidance for commissioners

4.1.1 The guideline offers best practice advice on the care of adults, children and young people with stage 4 or 5 CKD who have, or are at risk of, hyperphosphataemia. This includes primary, secondary and tertiary care settings.

4.1.2 Expenditure on the management of hyperphosphataemia will fall under the Programme Budgeting category of 17B – Problems of the genitourinary system: renal problems.

5 Conclusion

5.1.1 Implementation of the guideline is likely to reduce the number of people being prescribed sevelamer hydrochloride or lanthanum carbonate. The potential savings per person arising due to changes in prescribing are :

- Changing from sevelamer hydrochloride to either calcium carbonate or calcium acetate will result in annual savings of £2186 or £2096 per person respectively in adults.

- Changing from lanthanum carbonate to either calcium carbonate or calcium acetate will result in annual savings of £1806 or £1716 per person respectively in adults.

5.1.2 Due to the small number of children who would be affected by this guidance, commissioners are advised to calculate costs on a case by case basis.

5.1.3 There are also likely to be costs associated with the increase in the number of people receiving a dietary assessment with a specialist renal dietitian. The cost of an assessment with a specialist renal dietitian is estimated to be £74.00 per person (see 3.1.5 for details).

5.1.4 Commissioners are advised to check current practice in their local area and use the local costing template to ascertain the resource impact for their population.

Appendix A. Approach to costing guidelines