

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Patiromer for treating hyperkalaemia

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of patiromer within its marketing authorisation for treating hyperkalaemia.

Background

Hyperkalaemia means an abnormally high level of potassium in the blood (normal range 3.5 to 5.0 millimoles per liter [mmol/L]).¹ Many people with hyperkalaemia may not have any symptoms, whilst other people have muscle weakness, muscle stiffness or fatigue. Severe hyperkalaemia can cause irregular heart beat (arrhythmia) leading to cardiac arrest and death.

Hyperkalaemia usually occurs in people with impaired kidney function which may be caused by acute kidney injury or chronic kidney disease. Chronic kidney disease is prevalent among people with diabetes or chronic heart failure. Hyperkalaemia is common among people with end-stage renal disease and in the elderly. The risk of hyperkalaemia is increased further by medicines such as potassium supplements, inhibitors of renin–angiotensin–aldosterone system that include (angiotensin-converting-enzyme inhibitors [ACE], angiotensin II receptor blockers [ARB] and potassium-sparing diuretics). These medicines are used to treat high blood pressure and heart failure often in people with chronic kidney disease.

Between 1% and 10% of hospital inpatients have hyperkalaemia.² It is not known how many outpatients have the condition. Hyperkalaemia is observed in about 10% of people using ACE inhibitors and ARBs.¹ It is also present in about 5% to 10% of people having regular haemodialysis and about 10% of people with kidney failure who are not on dialysis.² In 2013-14 there were around 7,000 hospital admissions for hyperkalaemia in England resulting in around 21,000 bed days.³

The European Resuscitation Council classifies hyperkalaemia as mild (serum potassium level of 5.5 to 5.9 mmol/l), moderate (6.0-6.4 mmol/l) or severe (6.5 mmol/l and above).¹ Treatment options for mild and moderate hyperkalaemia include a low-potassium diet and stopping medicines that cause hyperkalaemia. Further options include sodium polystyrene sulphonate or calcium polystyrene sulphonate, which reduce the levels of potassium in the body.

NICE clinical guideline 169 recommends that people with acute kidney injury who have hyperkalaemia that is not responding to medical management

should be referred for renal replacement therapy immediately. To prevent hyperkalaemia, NICE clinical guideline 182 recommends the cautious use of renin–angiotensin system antagonists (ACE inhibitors and ARBs) in people with chronic kidney disease.

The technology

Patiromer (Veltassa, Vifor Pharma) is a non-absorbed, cation-exchange polymer. It works by binding free potassium ions in the gastrointestinal tract and releasing calcium ions for exchange, thus lowering the amount of potassium available for absorption into the blood stream and increasing the amount that is excreted via the faeces. It is administered orally.

Patiromer has a UK marketing authorisation for the treatment of hyperkalaemia in adults.

Intervention(s)	Patiromer
Population(s)	Adults with hyperkalaemia
Comparators	Established clinical management without patiromer. This may include but is not limited to, low-potassium diet, stopping medicines that cause hyperkalaemia and sodium or calcium polystyrene sulphonate.
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • serum potassium level • episodes of severe hyperkalaemia (serum potassium level 6.5 mmol/L or above) • cardiac arrhythmia • overall survival • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> • people with chronic kidney disease • people on renin–angiotensin–aldosterone system inhibitors • people with diabetes mellitus • people with heart failure <p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
Related NICE recommendations and NICE Pathways	<p>Related Guidelines:</p> <p>Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy (2013). NICE Clinical Guideline 169.</p> <p>Chronic kidney disease in adults: assessment and management (2015) NICE Clinical Guideline 182.</p> <p>Related Quality Standards:</p> <p>Chronic kidney disease in adults (July 2017). NICE quality standard 5. https://www.nice.org.uk/guidance/qs5</p> <p>Related NICE Pathways:</p> <p>Acute kidney injury. NICE pathway: http://pathways.nice.org.uk/pathways/acute-kidney-injury</p> <p>Chronic kidney disease. NICE pathway: http://pathways.nice.org.uk/pathways/chronic-kidney-disease</p> <p>Hypertension. NICE pathway: http://pathways.nice.org.uk/pathways/hypertension</p>
Related National Policy	<p>Manual for Prescribed Specialised Services 2016/17. Chapter 15 ‘Adult specialists renal services’ page 52. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf</p> <p>National Service Framework for Renal Services: http://www.nhs.uk/NHSEngland/NSF/Pages/Renalservi</p>

	ces.aspx Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1,2,3 and 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017
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Questions for consultation

Have all relevant comparators for patiromer been included in the scope?
 Which treatments are considered to be established clinical practice in the NHS for hyperkalaemia?

Are the outcomes listed appropriate?

Are there any other subgroups of people in whom patiromer is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider patiromer will fit into the existing NICE pathways on [acute kidney injury](#), [chronic kidney disease](#) and [hypertension](#)?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which patiromer is licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider patiromer to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of patiomer can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmg19/chapter/1-Introduction>).

NICE has published an addendum to its guide to the methods of technology appraisal (available at <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf>), which states the methods to be used where a cost comparison case is made. We welcome comments on the appropriateness and suitability of the cost comparison methodology to this topic.

- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. European Resuscitation Council (2015) [Guidelines for Resuscitation](#): 2015, Section 4. Cardiac arrest in special circumstances. Accessed September 2017.
2. The Renal Association (2014) [Clinical Practice Guideline on Treatment of Acute Hyperkalaemia in Adults](#). Accessed September 2017.
3. Health and Social Care Information Centre, Hospital Episode Statistics for England. Inpatient statistics, 2013-14. www.hscic.gov.uk