NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Sodium zirconium cyclosilicate for treating hyperkalaemia

Final scope

Remit/Appraisal objective

To appraise the clinical and cost effectiveness of sodium zirconium cyclosilicate 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 older people. 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 often used to treat high blood pressure and heart failure in people with chronic kidney disease. Some people with chronic kidney disease have chronic acidosis, which is treated using sodium bicarbonate which would lower the risk of hyperkalaemia[4].

Between 1% and 10% of hospital inpatients have hyperkalaemia.[2] 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 108 ‘Chronic heart failure in adults: management’ recommends closely monitoring potassium, creatinine levels, and estimated

glomerular filtration rate (eGFR) in people with heart failure due to left ventricular systolic dysfunction who are taking aldosterone antagonists and/or ARBs. It also recommends specialist advice, if the patient develops hyperkalaemia or renal function deteriorates. 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

Sodium zirconium cyclosilicate (Lokelma, Astra Zeneca) is a potassium binder. It contains an insoluble, non-absorbed zirconium silicate with a structure designed to trap potassium ions. This lowers the amount of potassium available for absorption into the blood stream and increases the amount that is excreted in faeces. It is administered orally as a suspension in water.

Sodium zirconium cyclosilicate has a marketing authorisation in the UK for the treatment of hyperkalaemia in adult patients.

Intervention(s)	Sodium zirconium cyclosilicate
Population(s)	Adults with hyperkalaemia
Comparators	Standard care. This includes a low-potassium diet with or without agents that reduce levels of potassium in the body
Outcomes	The outcome measures to be considered include: • serum potassium level • use of renin–angiotensin–aldosterone system inhibitor therapy • mortality • time to normalisation • 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	If the evidence allows the following subgroups will be considered: • people with acidosis • people with acute hyperkalaemia • people with chronic kidney disease • people with heart failure 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.
Related NICE recommendations and NICE Pathways	**Related Technology Appraisals:** 'Patiromer for treating hyperkalaemia'. Proposed NICE technology appraisal [ID 877]. Publication date to be confirmed. **Related Guidelines:** Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy (2013). NICE Clinical Guideline 169. Chronic kidney disease in adults: assessment and management (2015) NICE Clinical Guideline 182. Chronic heart failure in adults: management (2010) NICE Clinical Guideline 108. **Related Quality Standards:** Chronic kidney disease in adults (July 2017). NICE quality standard 5. https://www.nice.org.uk/guidance/qs5 **Related NICE Pathways:**

	Acute kidney injury. NICE pathway: http://pathways.nice.org.uk/pathways/acute-kidney-injury Chronic kidney disease. NICE pathway: http://pathways.nice.org.uk/pathways/chronic-kidney-disease Hypertension. NICE pathway: http://pathways.nice.org.uk/pathways/hypertension
Related National Policy	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 National Service Framework for Renal Services: http://www.nhs.uk/NHSEngland/NSF/Pages/Renalservices.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

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
4. Evans KJ, Greenberg A. Hyperkalemia: a review. J Intensive Care Med. 2005;20(5):272-90.