NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Sodium zirconium cyclosilicate for treating hyperkalaemia (TA599)

Published: September 2019

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Summary

NICE has recommended sodium zirconium cyclosilicate as an option for treating hyperkalaemia in adults, only if used in emergency care for acute life-threatening hyperkalaemia alongside standard care, or for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or, heart failure (see section 1).

We estimate that:

- 13,600 people with acute life-threatening hyperkalaemia or with persistent hyperkalaemia are eligible for treatment with sodium zirconium cyclosilicate.
- 8,170 people will have sodium zirconium cyclosilicate (4,900 in emergency care and 3,270 with persistent hyperkalaemia when started in specialist care) from year 2023/24 onwards once uptake has reached 60% (36% emergency care and 24% for people with persistent hyperkalaemia) as shown in table 1. Ongoing treatment for people with persistent hyperkalaemia could be in either secondary care or in a primary care setting.

Table 1 Estimated number of people in England receiving treatment with sodium zirconium cyclosilicate

People treated each year	2019/20	2020/21	2021/22	2022/23	2023/24
Emergency care[1]	1,550	3,810	4,760	4,660	4,900
Persistent hyperkalaemia[1]	80	950	2,040	3,100	3,270
Total	**1,630**	**4,760**	**6,800**	**7,760**	**8,170**

[1] Numbers rounded to the nearest 10

This report is supported by a local resource impact template because costs may vary in different settings because of negotiated procurement discounts. The discounted price can be put into the template and other variables may be amended.

This technology is commissioned by integrated care systems/ clinical commissioning groups. Providers are NHS hospitals and primary care.

1 Sodium zirconium cyclosilicate

1.1 NICE has recommended sodium zirconium cyclosilicate for treating hyperkalaemia in adults only if used:

- in emergency care for acute life-threatening hyperkalaemia alongside standard care or
- for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they:
  - have a confirmed serum potassium level of at least 6.0 mmol/litre and
  - because of hyperkalaemia, are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) and
  - are not on dialysis.

Stop sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable.

1.2 Hyperkalaemia is a high level of potassium in the blood. Hyperkalaemia occurs most commonly in people with chronic kidney disease (3b to 5), and heart failure.

1.3 Patients in the NHS with serum potassium levels above the normal range do not always need treatment to lower potassium. The need for, and type of, treatment for hyperkalaemia depends on its severity. Life-threatening acute hyperkalaemia needs emergency treatment in hospital.

1.4 NICE-accredited clinical practice guidelines for treating acute hyperkalaemia from the UK Renal Association state that the risk of cardiac arrhythmias increases with serum potassium levels above 6.5 mmol/litre. Small rises in serum potassium above this can cause ECG changes. To lower the risk of cardiac arrest, clinicians use active potassium-lowering treatments, then identify and remove the cause of hyperkalaemia.

2 Resource impact of the guidance

2.1 We estimate that:

- 13,600 people with acute life-threatening hyperkalaemia or with persistent hyperkalaemia are eligible for treatment with sodium zirconium cyclosilicate.
- 8,170 people will have sodium zirconium cyclosilicate (4,900 in emergency care and 3,270 with persistent hyperkalaemia when started in specialist care) from year 2023/24 onwards once uptake has reached 60% (36% emergency care and 24% for people with persistent hyperkalaemia). Ongoing treatment for people with persistent hyperkalaemia could be in either secondary care or in a primary care setting.

2.2 The current treatment and future uptake figure assumptions are based on company and published evidence and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have sodium zirconium cyclosilicate by financial year.

Table 2 Estimated number of people receiving treatment with sodium zirconium cyclosilicate using NICE assumptions

People treated each year	2019/20	2020/21	2021/22	2022/23	2023/24
Emergency care[1]	1,550	3,810	4,760	4,660	4,900
Persistent hyperkalaemia[1]	80	950	2,040	3,100	3,270
Total	**1,630**	**4,760**	**6,800**	**7,760**	**8,170**

[1] Numbers rounded to the nearest 10

2.3 This report is supported by a local resource impact template because the costs may vary in different settings because of negotiated procurement discounts. The discounted price can be put into the template and other variables may be amended.

Benefits

2.4 Clinical trials show that sodium zirconium cyclosilicate lowers serum potassium. Therefore, it may allow people to stay on renin-angiotensin-aldosterone system inhibitors (drugs used to treat heart failure and kidney disease) for longer. Staying on these drugs may extend life and improve quality of life for adults with hyperkalaemia.

3 Implications for commissioners

3.1 This technology is commissioned by integrated care systems/ clinical commissioning groups. Providers are NHS hospitals and primary care.

3.2 Sodium zirconium cyclosilicate falls within the programme budgeting category PBC04X: Endocrine, Nutritional and Metabolic problems.

4 How we estimated the resource impact

The population

4.1 Table 3 shows the number of people eligible for treatment with sodium zirconium cyclosilicate.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Adult population in England **(18 years or older)**		43,752,473
People with Chronic Kidney Disease (CKD)		
Diagnosed prevalence of chronic kidney disease G3a-G5 (previously stages 3a-5) [1]	4.11	1,798,230
People with stages 3b—5 CKD[2]	33.33	599,350
People with stages G3b—5 chronic kidney disease with hyperkalaemia and likely to have serum potassium level of at least 6.0 mmol/litre[3] **(A)**	2.6	15,580
People with Heart Failure		
Population in England (all ages)		55,619,430
Prevalence of heart failure[1]	0.83	462,580
People with heart failure with hyperkalaemia and likely to have serum potassium level of at least 6.0 mmol/litre[4] **(B)**	3.17	14,660
Total number of people with stages G3b—5 chronic kidney disease and heart failure, with hyperkalaemia and likely to have serum potassium level of at least 6.0 mmol/litre (A+B)	**N/A**	**30,240**
Number of people with stages G3b—5 chronic kidney disease and heart failure, with hyperkalaemia and likely to have a confirmed serum potassium level of at least 6.0 mmol/litre who are treated[5]	45	13,600
Total number of people estimated to have sodium zirconium cyclosilicate each year from year 2023/24[5]	**60**	**8,170**

[1] NHS Digital. https://digital.nhs.uk/data-and-information/publications/statistical/quality-and-outcomes-framework-achievement-prevalence-and-exceptions-data/2017-18.
For heart failure, this is a whole population prevalence. However, because heart failure affects mostly older people it is assumed that the majority of the prevalent population are adults (18 years or older).

[2] Gifford F, Methven S, Boag D, Spalding E, Macgregor M. Chronic kidney disease prevalence and secular trends in a UK population: the impact of MDRD and CKD-EPI formulae. QJM: An International Journal of Medicine. 2011;104(12):1045-53.

[3] https://academic.oup.com/ndt/article/33/9/1610/4644812

[4] https://www.ahajournals.org/doi/full/10.1161/JAHA.118.008912

[5] Company submission.

For further details on the source in this table see the resource impact template: Assumptions worksheet.

Assumptions

4.2 The resource impact template assumes that:

- Calcium resonium is the comparator treatment. It is the current standard care and is used only in an emergency care setting.
- Treatments cost of sodium zirconium cyclosilicate is based on an initial dose 10 g 3 times a day, for up to 72 hours, for the correction phase, followed by maintenance 5 g once daily, adjusted according to serum-potassium concentrations. The usual maintenance dose range is 5 g once every other day to 10 g once daily. The model assumed used 5g daily for the maintenance treatment. The model can be used to amend the percentage mix of doses used per day or every other day in the maintenance treatment.
- The treatment cost in the emergency care setting is based on a 30-day treatment duration. However, clinical experts suggest that treatment could be only for a few days in emergency care, rather than 30 days. Sodium Zirconium Cyclosilicate is available in either 10g (30 sachet pack or 3 sachet pack) or 5g (30 sachet pack). Therefore, the cost could be lower if sachets could be issued in single form rather than as a 30-day or 3-day sachet pack.
- Treatment cost of sodium zirconium cyclosilicate for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure is based on a full year. The NICE recommendation for use of sodium zirconium cyclosilicate to treat hyperkalaemia does not have a treatment duration-based stopping rule.
- No additional administration or monitoring costs over standard care are associated with sodium zirconium cyclosilicate.

Other factors

4.3 The guidance recommends stopping sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable. There are no estimates in the model to account for this as no robust data are available.

4.4 The company highlighted that the use of sodium zirconium cyclosilicate is expected to lead to:

- cost-savings associated with decreased number of emergency admissions of hyperkalaemia events because of better potassium control on sodium zirconium cyclosilicate, and
- cost-savings associated with decreased number of chronic kidney disease, heart failure, major adverse cardiac event, and the associated hospitalisation costs.

Because the committee emphasised that uncertainties remained around the clinical benefit of sodium zirconium cyclosilicate and that these could not be addressed without further clinical trials, the savings have not been included.

About this resource impact report

This resource impact report accompanies the NICE guidance on sodium zirconium cyclosilicate for treating hyperkalaemia and should be read with it.