NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Patiromer for treating hyperkalaemia (TA623)

Published: February 2020

Summary

NICE has recommended patiromer 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 patiromer.
- 4,100 people will have patiromer (2,500 in emergency care and 1,600 with persistent hyperkalaemia when treatment is started in hospital) from 2023/24 onwards once uptake has reached 30% (18% emergency care and 12% for people with persistent hyperkalaemia when treatment is started in hospital) 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 patiromer

People treated each year	2019/20	2020/21	2021/22	2022/23	2023/24
Emergency care	780	1,900	2,200	2,300	2,500
Persistent hyperkalaemia	40	500	900	1,600	1,600
Total	**820**	**2,400**	**3,100**	**3,900**	**4,100**

This report is supported by a local resource impact template because the list price of one of the other treatment options, sodium zirconium cyclosilicate has a discount that is commercial in confidence. The discounted price can be put into the template and other variables may be amended.

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

1 Patiromer

1.1 NICE has recommended patiromer 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
  - are not taking, or are taking a reduced dosage of, a renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and
  - are not on dialysis.

Stop patiromer 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 (stages 3b to 5), and heart failure.

1.3 People 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 Treating acute life-threatening hyperkalaemia in emergency care is established clinical practice. Other potassium-lowering treatments are rarely used in this setting because they are poorly tolerated. Patiromer could be a useful addition to emergency care.

1.5 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 patiromer.
- 4,100 people will have patiromer (2,500 in emergency care and 1,600 with persistent hyperkalaemia when treatment is started in hospital) from 2023/24 onwards once uptake has reached 30% (18% emergency care and 12% for people with persistent hyperkalaemia when treatment is started in hospital). 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 the company submission and published evidence and are shown in the resource impact template.

2.3 Table 2 shows the number of people in England who are estimated to have patiromer by financial year.

Table 2 Estimated number of people receiving treatment with patiromer using NICE assumptions

People treated each year	2019/20	2020/21	2021/22	2022/23	2023/24
Emergency care	780	1,900	2,200	2,300	2,500
Persistent hyperkalaemia	40	500	900	1,600	1,600
Total	**820**	**2,400**	**3,100**	**3,900**	**4,100**

2.4 This report is supported by a local resource impact template because the list price of the other treatment option sodium zirconium cyclosilicate has a discount that is commercial in confidence. The discounted price can be put into the template and other variables may be amended.

Benefits

2.5 Clinical trials show that patiromer lowers serum potassium, but there is no clinical evidence that it extends life or improves quality of life. Patiromer may allow people to stay on RAAS inhibitors (drugs used to treat heart failure and kidney disease) for longer. Staying on these drugs may extend life and improve quality of life.

2.6 Patiromer can be prescribed in primary care for people with confirmed persistent hyperkalaemia whose treatment is started in hospital.

3 Implications for commissioners

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

3.2 Patiromer 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 patiromer.

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 G3b-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)**	2.60	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]	45.00	13,600

[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 most 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] Based on NICE Technology appraisal guidance 599 company submission.

4.2 Table 4 shows the number of people in England who are estimated to receive each of the three treatments each year from 2023/24.

Table 4 Number of people receiving each of the treatments each year from year 2023/24 in England

Population	Proportion of previous row (%)	Number of people
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	**45.00**	**13,600**
Analysis of treatments		
Number of people estimated to have patiromer in emergency care setting each year from year 2023/24[1]	18.00	2,450
Number of people estimated to have patiromer in secondary care/primary care each year from year 2023/24[1]	12.00	1,630
Number of people estimated to have sodium zirconium cyclosilicate in emergency care setting each year from year 2023/24[1]	18.00	2,450
Number of people estimated to have sodium zirconium cyclosilicate in outpatient setting each year from year 2023/24[1]	12.00	1,630
Number of people estimated to have calcium resonium in emergency care setting each year from year 2023/24[1]	40.00	5,440
Total number of people treated		**13,600**

[1] The market share of patiromer is 30% and sodium zirconium cyclosilicate is 30%. (This is an equal split of the 60% market share used for sodium zirconium cyclosilicate in TA599). See the resource impact template for further details of the sources listed in this table.

Assumptions

4.3 The resource impact template assumes that:

- Calcium resonium and sodium zirconium cyclosilicate are the comparator treatments. Calcium resonium is the current standard care and is used only in an emergency care setting.
- Patiromer would be used in both the emergency care setting, and in primary care for persistent hyperkalaemia when started in hospital. The proportion of people treated in the emergency care setting and with persistent hyperkalaemia is in line with the resource impact template for the NICE technology guidance 599 (Sodium zirconium cyclosilicate for treating hyperkalaemia)
- The annual treatment cost of patiromer is based on a dose of 8.4g daily. However, this can be increased up to a maximum of 25.2g daily. Therefore, treatment cost would be higher where daily dose required is 25.2g. The model can be used to the calculate average treatment cost based on both minimum daily dose and maximum daily dose.
- The treatment cost in the emergency care setting is based on a 30-day sachet pack. However, clinical experts suggest that treatment could be only for a few days in emergency care, rather than 30 days. Patiromer is available in a 30-sachet pack. It is assumed that packs are not split. Therefore, the cost could be lower if sachets could be issued in single form rather than as a 30-day sachet pack. The model can be used to calculate the cost.
- For people with persistent hyperkalaemia the treatment cost is based on a full year treatment duration. Ongoing treatment for people with persistent hyperkalaemia could be in either secondary care or in a primary care setting.
- The model assumes that all people with persistent hyperkalaemia are treated in secondary care. However, the template can be amended to estimate costs for people treated in primary care. Treatment in primary care would attract no value added tax (VAT) and the template calculates VAT only for

people with persistent hyperkalaemia who are treated in secondary care.

- No additional administration or monitoring costs over standard care are associated with patiromer. It is assumed that treatment will be in existing appointments for these people.

Other factors

4.4 Patiromer can be prescribed in primary care for people with confirmed persistent hyperkalaemia whose treatment started in hospital.

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

4.6 The company highlighted that the use of patiromer is expected to lead to:

- cost-savings associated with decreased risk of cardiovascular events and chronic kidney disease progression because of better potassium control on patiromer, and
- cost-savings associated with decreased number of hyperkalaemia hospitalisation costs.

The committee was aware of DIAMOND, an ongoing randomised controlled trial of patiromer compared with placebo for adults with hyperkalaemia and heart failure. Its primary outcome was time to first occurrence of hospitalisation or death. The DIAMOND trial results may, in future, provide evidence for a link between patiromer and length of life.

The committee concluded that there was insufficient evidence to prove that lowering serum potassium levels for people in outpatient care improves outcomes. Therefore, these could not be addressed without further clinical trials and so any potential savings have not been included.

About this resource impact report

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