Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

NICE Technology Appraisals: Local implementation

NICE TA Guidance	Sodium zirconium cyclosilicate for treating hyperkalaemia (NICE TA599, updated 24 January 2022)		
Available at	https://www.nice.org.uk/guidance/ta599		
Date of issue	04 September 2019, updated 24 January 2022)	**Implementation deadline**	3 months from publication

Medicine details	
Name, brand name	Sodium zirconium cyclosilicate (Lokelma)
Manufacturer	AstraZeneca UK Limited
Licensed indication	"Lokelma is indicated for the treatment of hyperkalaemia in adult patients" (SPC 01/04/22)
Formulation	Powder for oral suspension (SPC 01/04/22)
Usual dosage	"Initially 10 g 3 times a day, for up to 72 hours, 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." (BNF 01/04/22)
NICE recommended dosage/schedule	As per Section 2 of TA.

Disease and potential patient group	
Brief description of disease	Hyperkalaemia is a high level of potassium in the blood. The European Resuscitation Council classifies hyperkalaemia as mild (serum potassium level of 5.5 mmol/litre to 5.9 mmol/litre), moderate (6.0 mmol/litre to 6.4 mmol/litre) or severe (6.5 mmol/litre and above). The need for, and type of, treatment for hyperkalaemia depends on its severity. Life-threatening acute hyperkalaemia needs emergency treatment in hospital. 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.
Potential patient numbers per 100,000	NICE estimate that for the whole population of England: • 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.

NICE resource impact template.

Number of people treated by care setting and by type of treatment						
Financial year	Current practice	2019/20	2020/21	2021/22	2022/23	2023/24
Emergency care						
Calcium resonium	251	221	163	138	108	100
Sodium zirconium cyclosilicate	-	14	35	40	43	45
Patiromer	-	14	35	40	43	45
Outpatient care						
Sodium zirconium cyclosilicate	-	1	9	17	29	30
Patiromer	-	1	9	17	29	30
Primary care						
Sodium zirconium cyclosilicate	-	-	-	-	-	-
Patiromer	-	-	-	-	-	-
Total	**251**	**251**	**251**	**251**	**251**	**251**
Drug costs by care setting and by type of treatment						
Emergency care						
Calcium resonium	£12,311	£10,833	£8,002	£6,771	£5,294	£4,924
Sodium zirconium cyclosilicate	£0	£670	£1,646	£1,852	£2,011	£2,116
Patiromer	£0	£2,470	£6,067	£6,826	£7,411	£7,801
Total	**£12,311**	**£13,974**	**£15,715**	**£15,448**	**£14,715**	**£14,841**
Outpatient care						
Sodium zirconium cyclosilicate	£0	£1,466	£17,101	£32,981	£55,701	£58,632
Patiromer	£0	£1,582	£18,455	£35,591	£60,110	£63,274
Total	**£0**	**£3,048**	**£35,556**	**£68,572**	**£115,811**	**£121,906**
Primary care						
Sodium zirconium cyclosilicate	£0	£0	£0	£0	£0	£0
Patiromer	£0	£0	£0	£0	£0	£0
Total costs	**£12,311**	**£17,021**	**£51,271**	**£84,021**	**£130,526**	**£136,748**
Drug costs (including VAT)						
Calcium resonium	£14,773	£13,000	£9,602	£8,125	£6,352	£5,909
Sodium zirconium cyclosilicate	£0	£2,563	£22,497	£41,799	£69,254	£72,899
Patiromer	£0	£4,863	£29,427	£50,901	£81,025	£85,289
Patiromer (primary care No VAT)	£0	£0	£0	£0	£0	£0
Total drug costs (including	**£14,773**	**£20,426**	**£61,525**	**£100,825**	**£156,631**	**£164,097**

	VAT)						
	Total resource impact (including VAT)	**£0**	**£5,653**	**£46,753**	**£86,052**	**£141,858**	**£149,324**

SUMMARY

NICE recommendation

Update January 2022: Changes were made to recommendations 1.1 and 1.2 because sodium zirconium cyclosilicate is now available in both primary and secondary care. Section 2 was also updated because the patient access scheme for sodium zirconium cyclosilicate has been withdrawn. Section 1 changes are highlighted in yellow below.

The TA used to read as follows:
Sodium zirconium cyclosilicate is recommended as an option for treating hyperkalaemia in adults only if used:

- in emergency care for acute life-threatening hyperkalaemia alongside standard care or
- in outpatient care 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 an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and
  - are not on dialysis.

The TA now reads as follows:
Sodium zirconium cyclosilicate is recommended 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, 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) inhibitor and
  - are not on dialysis.

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

So "outpatient care" has been removed from the 2nd criteria, and the criteria around RAAS inhibitors has been reworded. The guidance to stop the sodium zirconium cyclosilicate when patient is no longer using RAAS inhibitors is also new. Changes are highlighted in the original wording in yellow above.

Cost implications*

Cost of product: NICE TA, therefore funding is mandatory and is subject to a budgetary uplift from DOHSC.
NHS indicative price – 5g sachets (30) = £156.00, 10g sachets (30) = £312.00

The list price of sodium zirconium cyclosilicate is £10.40 per 10-g sachet or £5.20 per 5-g sachet (company information, November 2021).
Costs may vary in different settings because of negotiated procurement discounts.

Annual cost per patient: Based on max. dose of 10g daily = £3,796 per annum.

Has dose escalation been considered as part of the NICE costing template? No dose

escalation is described in the SPC, and therefore it has not been considered by NICE. If product license changes over time, it is possible that further dose escalation calculations might be required.

Costing information/100,000 population and per CCG:
The CCG will be reimbursed by budgetary uplift as per NICE cost impact calculations (see above).

Availability of PAS and details (if appropriate): No (this has been removed since original publication allowing for treatment in primary care).

Availability of homecare service (if appropriate): No

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:
Patiromer (TA623) – RED on PAD

Options not reviewed by NICE but used in standard practice:
Calcium resonium is the comparator treatment. It is the current standard care and is used only in an emergency care setting.

• Treatment 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.

Impact to patients

- Until a specialist centre produces a shared care document which is adopted by the APC these patients will have to continue to travel to their specialist centre for their prescriptions for the foreseeable future.
- No other changes noted from previous decision

Impact to primary care prescribers

- Little to no impact to primary care until a shared care document is agreed by the APC.
- No other changes noted from previous decision

Impact to secondary care

- Tertiary centres will be required to maintain treatment of patients until a shared care document is agreed at APC.
- No other changes noted from previous decision

Impact to CCGs

- CCG budget will have been uplifted as per NICE cost calculation.
- No other changes noted from previous decision

Implementation

- Tertiary specialist centres should ensure that the drug is added to their drug formulary via the Trust DTC process(es) and that Trust pharmacies have suitable supply arrangements in place for patient access in time for the 90 day implementation deadline.
- Any trust pathways will need to be amended accordingly, due attention should be paid to deprescribing, stopping criteria and polypharmacy issues for this cohort of patients.
- No other changes noted from previous decision

Recommendation to APC

PbRe: No

Recommended traffic light status (see attached guidelines):

In light of the wording in the guidance which states that the drug should only be 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

and because there is a variability amongst neighbouring APC decisions regarding the need for shared care

and because of time pressures following TA publication, the author recommends that the APC awards this drug a **RED** traffic light status and that this drug should only be used in secondary/tertiary care at this time.

The alternative is to consider a shared care arrangement, either with or without a formal document:
Amber - as per York & Scarborough CCG – see ref 2
Blue (with/without info sheet) – as per Brighton & Hove CCG. APC would need to confirm details of this in meeting.

Q. Does the APC want the CVD workstream to prioritise this shared care work over other work on the CVD workplan (already over-pressed and under-resourced)? Is it in the patient's best interest to wait for someone from specialist service to develop a shared care arrangement? Is this decision putting patients at risk? Note; not on RMOC workplan, not on SPS Drug Monitoring Lookup (ref. 3).

Additional comments:

OpenPrescribing.net
Since September 2021, Surrey Heartlands CCG FP10 prescribing of sodium zirconium cyclosilicate has been to the value of £4067.85.

Prescribing information from local trusts

- SASH - treated 20 patients with 5g (£4250) and 67 patients with 10g (£16500), they do not have a trust-specific guideline for this treatment.
- RSFT – treated 10 patients, they do not have a trust-specific guideline for this treatment.
- ASPH – treated 38 patients, they do not have a trust-specific guideline for this treatment.
- ESHUT – information request outstanding

Other local APC status
SWL: awaiting RAG status
CHMS: Red (Sep19)
Brighton & Hove: Purple (specialist initiation without shared care)
Greater Manchester : awaiting RAG status

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Declaration of Interest: None

Date: 1st April 2022

Reviewed by:

Name, Designation, Organisation

Declaration of Interest:

XXXX

Date: XXXX

References

1. NICE TA Briefing paper from APC decision in December 2019 - Sodium Zirconium Cyclosilicate NICE TA599 - Briefing paper Dec19.pdf (res-systems.net)
2. York & Scarborough shared care (from September 2019) - (yorkandscarboroughformulary.nhs.uk)
3. SPS Drug Monitoring lookup **-** https://www.sps.nhs.uk/home/guidance/drug-monitoring/

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1				*Out for consultation*
v.2				