

UPDATED
NICE TAG:



**LOWER THE
THRESHOLD**

5.5

**RAISE
THE BAR**



Act from serum $K^+ \geq 5.5\text{mmol/L}$ with LOKELMA

NICE TA1148 now recommends LOKELMA for persistent hyperkalaemia in patients with CKD stages 3b-5 or HF patients and serum $K^+ \geq 5.5\text{mmol/L}$. The update provides greater flexibility across care settings, allowing treatment initiation in both primary and secondary care.*¹

Raise the bar for your eligible cardiorenal patients

The NICE expansion was driven by real-world evidence, which indicated:

- **SPARK:** Serum K^+ levels from 5.5mmol/L are independently associated with an increased risk of mortality, hospitalisation and major adverse cardiac outcomes.^{1,3,4}
- **ZORA:** Eligible patients treated with LOKELMA maintained RAASi therapy from 5.5mmol/L .^{1,5}

NICE determined that LOKELMA provides benefits and value for money, so it can be routinely used across the NHS in this population.¹

*LOKELMA (Sodium zirconium cyclosilicate) can be used as an option for treating hyperkalaemia in adults only if used: in emergency care for acute life-threatening hyperkalaemia alongside standard care or for persistent hyperkalaemia in people with chronic kidney disease stage 3b to 5 or heart failure, if they: have confirmed serum potassium level of at least 5.5mmol per litre and because of hyperkalaemia, are not taking an optimised dosage of renin-angiotensin aldosterone system (RAAS) inhibitor and are not on dialysis.^{1,2}

SPARK: the impact of serum K⁺ on clinical outcomes

Elevated serum K⁺ ≥5.5mmol/L is independently associated with poorer patient outcomes.³

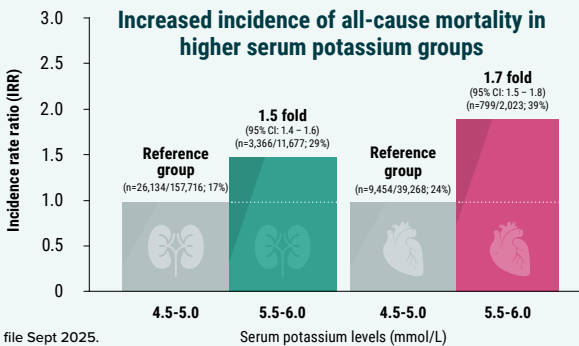
SPARK is a real-world observational study in ~630K eligible CKD or HF patients in the UK, specifically designed to directly evaluate the relationship between serum K⁺ and adverse outcomes. The study was designed in line with the NICE RWE framework.^{*3}

In patients with **CKD** or **HF**, serum K⁺ ≥5.5mmol/L was associated with:

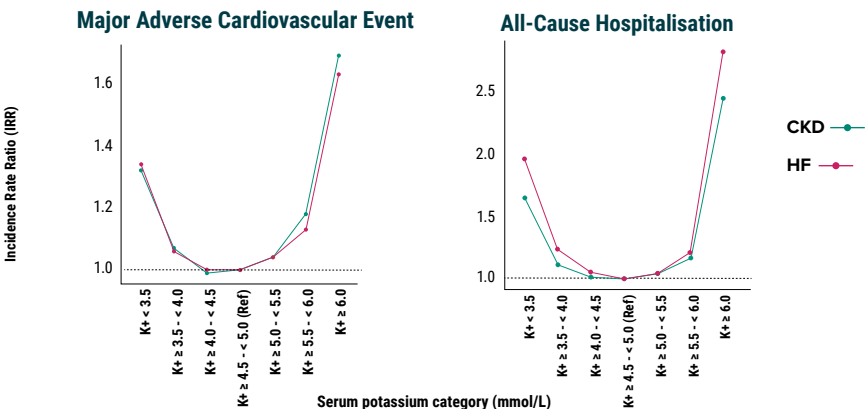
~50% & ~70%

higher risk of all-cause mortality, versus K⁺ 4.5-5.0mmol/L.^{*3}

Graph adapted from AstraZeneca SPARK study. Data on file Sept 2025.



Patients with CKD or HF and serum K⁺ ≥5.5mmol/L also experience meaningfully higher rates of hospitalisation and MACE, compared to K⁺ 4.5-5.0mmol/L.^{*3,4}



^{*}SPARK was a retrospective observational study using data from the Clinical Practice Research Datalink (CPRD), linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality data (2004–2021). Patients with an index serum potassium measurement (2016–2019) and evidence of hyperkalaemia or potassium binder use in CPRD were included.^{3,4}

ZORA: the impact of LOKELMA on RAASi therapy maintenance

Initiate LOKELMA from ≥ 5.5 mmol/L to manage hyperkalaemia, and help maintain RAASi therapy in eligible patients with CKD and/or HF.^{1,2,5}

ZORA is a real-world observational cohort study that assesses the odds of continuing RAASi therapy at 6 months in patients with CKD and/or HF experiencing hyperkalaemia, comparing those treated with LOKELMA to those receiving no K⁺ binder.*⁵

In eligible patients with serum K⁺ 5.5–6.0 mmol/L, a higher proportion maintained RAASi therapy with LOKELMA.⁵

Increased by:
42%
In the US
0.68 vs 0.48; p<0.0006⁺
(n=97 treated / 365 untreated)

Increased by:
59%
In Japan
0.63 vs 0.40; p=0.0009⁺
(n=82 treated / 158 untreated)

compared with the no K⁺ binder cohort.

Observations from ZORA real-world evidence are consistent with the randomised controlled trials used to establish the LOKELMA Summary of Product Characteristics.^{2,5}

*The study, funded by AstraZeneca, was an observational, cohort study programme performed using secondary data extracted from health registers and hospital medical records from the US, Spain and Japan. The primary outcome of the ZORA analysis conducted by Rastogi et al. (2024) was the proportion of patients who maintained RAASi therapy at 180 days post-index. The objective of the additional subgroup analysis of ZORA was to determine the proportions of patients discontinuing or down-titrating RAASi therapy stratified by recorded S–K levels (≥ 5.0 –<5.5 mmol/L, ≥ 5.5 –<6.0 mmol/L, and ≥ 6.0 mmol/L).^{5,8}

⁺Based on nominal significance level of p=0.05

LOKELMA – Safety and Prescribing Information

Worsening of pre-existing heart failure during treatment was reported as a very common adverse reaction where most cases were resolved with appropriate clinical management without withdrawing Lokelma. The commonly reported adverse reactions were hypokalaemia, oedema related events and constipation.²

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting: <https://contactazmedical.astrazeneca.com/> or by calling **0800 783 0033**.

Click or scan the QR code for UK LOKELMA prescribing information:



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NICE have lowered the threshold.

NICE TA1148 now aligns more closely with international guidance (ESC & KDIGO), emphasising action from serum $K^+ \geq 5.5 \text{ mmol/L}$.^{1,6,7}



**Act from $K^+ \geq 5.5 \text{ mmol/L}$ with LOKELMA to
raise the bar for your patients.**

**Reduce the risks of elevated serum K^+ . Help enable RAASI
therapy continuation. Maintain long-term cardiorenal protection.**



Click or scan the QR code

to access resources supporting LOKELMA use in patients with
 $K^+ \geq 5.5 \text{ mmol/L}$, and materials to help update your local formulary.

QR code links to AstraZeneca promotional site.

Abbreviations:

K^+ , Potassium ; $\geq$, Greater than or equal to; mmol/L, Millimoles per litre; NICE, National Institute for Health and Care Excellence; TA, Technology appraisal; CKD, Chronic kidney disease; HF, Heart failure; RAASI, Renin-angiotensin aldosterone system inhibitors; NHS, National Health Service; MACE, Major adverse cardiovascular events; SmPC, Summary of product characteristics. ESC, European Society of Cardiology; KDIGO, Kidney Disease Improving Global Outcomes.

References:

1. Sodium zirconium cyclosilicate for treating hyperkalaemia (2026) NICE Technology Appraisal Guidance 1148; 2. AstraZeneca. LOKELMA (sodium zirconium cyclosilicate) Summary of Product Characteristics, United Kingdom.; 3. AstraZeneca. SPARK – Investigating the impact of serum potassium levels on clinical outcomes and treatment management strategies for patients with hyperkalaemia in UK clinical settings: an observational study. Data on file (REF-286448). September 2025; 4. AstraZeneca. UKKW 2025 Poster - Association of serum potassium levels with clinical outcomes and healthcare resource use in a large UK population – an observational study. PB 260, Burton et al., Data on file (REF-331348) June 2025; 5. AstraZeneca. ZORA re-analysis: RAASI use in patients with serum potassium $\geq 5.5 - < 6.0 \text{ mmol/L}$ on SZC or not on any K binder. Data on file (REF-336899) May 2026; 6. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. Kidney Int. 2024;105(4S):S117–S314; 7. McDonagh T.A., Metra M., Adamo M. et al. Eur Heart J. 2021;42(36):3599-3726. doi:10.1093/eurheartj/ehab368; 8. Rastogi et al. Clin Kidney J. 2024 Mar 25;17(5):sfae083.