NHS Lanarkshire
Template for Clinical Protocol for Introduction of New Medication

1. Medicine name & formulation

Sodium zirconium cyclosilicate (SZC) (Lokelma)

2. Licensed Indications

Treatment of hyperkalaemia - patients with hyperkalaemia (defined as a serum potassium of >6.0mmol/L) with chronic kidney disease (CKD) stage 3b to 5 and/or heart failure, who would otherwise need to down-titrate or discontinue their renin-angiotensin-aldosterone system inhibitor (RAASi) therapy to maintain a clinically acceptable serum potassium level (normokalaemia), and treatment of acute, life-threatening hyperkalaemia alongside standard care. Also licensed for use in renal dialysis patients.

3. Summary of National Guidance

recommended as an option in the management of persistent hyperkalaemia with serum K>/= 6.0 in outpatients with CKD 3b-5 (not on dialysis) or heart failure receiving a sub-optimal dose or not receiving RAASi due to hyperkalaemia, and as an option in the treatment acute life-threatening hyperkalaemia alongside standard care in hospitalised patients**.** (UK Renal Association – Clinical Practice Guidelines – Treatment of Acute Hyperkalaemia in Adults (June 2020))

4. Please Define Application for Use

Anticipated benefits of treatment

Note: If unlicensed use of medicine - please complete Physician Request Form for Non Licensed Medicine (proforma available on intranet under Drugs and Prescribing) and contact pharmacy for further information and advice.

Sodium zirconium cyclosilicate (SZC) (Lokelma) is a gastrointestinal cation exchangers which can be used for control of hyperkalaemia. This offers an alternative to Calcium Resonium, which is associated with serious gastrointestinal adverse effects and is highly unpalatable.
Suboptimal dosing of RAASi / MRA is associated with worse cardiovascular outcomes and higher mortality in patients with CKD and/or HF compared to optimal dosing.
Potassium lowering treatments may allow optimisation of RAASi dosing.
The evidence base for these medicines demonstrates improvements in serum potassium, but not extended or improved quality of life. Use of these medicines may allow patients to remain on medicines which have already been demonstrated to improve quality of life or extend life.

5. Proposed place in therapy in Lanarkshire. Please attach protocol which should include details of*:*

Attached protocols including use in:

- CKD HF
- Acute hyperkalaemia
- Dialysis patients

Indication	• Definition of clinical condition being treated • Treatment intent – e.g. curative, palliative etc.
Eligibility criteria	• Inclusion criteria • Exclusion criteria • Withdrawal criteria
Pre-Treatment Evaluation/Investigations	• Baseline investigations e.g. relevant biochemistry, LFT's, FBC etc. Any other tests specific to the drugs and the

delivery plan for these tests.

	Treatment Requirements	This must included for example • Dose and dosing schedule • Frequency • Duration / planned number of cycles • Method of administration – e.g., oral etc. • Who will administer the drug • Where will the drug be administered e.g. day case, outpatient clinic, inpatient, patient's home. • Pre-medication required • Supportive therapy if applicable • Treatment cycle frequency
	Precautions, contraindications and adverse effects	• Special precautions and contraindications to treatment. • Potential interactions and medicines to be avoided
	Investigations prior to subsequent treatment	• Baseline investigations e.g. relevant biochemistry, LFT's, FBC etc. Any other tests specific to the drugs and the delivery plan for these tests.
	Dose modifications e.g.	• Haematology • Renal Function • Hepatic Function •
	Audit / Evaluation of Response to Treatment	• How will clinical outcomes of this treatment be assessed • Method of evaluation • Frequency
6.	**Anticipated patient numbers per annum**	
	Service implications **Impact on nursing/medical duties** **Impact on pharmacy duties** **Impact on laboratory & imaging services** **Where will patients be treated?** **Has business plan been submitted?** These medicines will be introduced in secondary care, usually from clinics. This will take up medical / other HCP time. It is hoped that keeping people on or being able to initiate medicines with high prognostic value will reduce or delay ESRD and costly RRT, avoid cardiovascular morbidity and mortality and avoid hospital admissions. Hyperkalaemia contributes to frequent unscheduled care attendances and use of these medicines will hopefully enable admission avoidance. These medicines will often replace the use of calcium resonium, so will often be cost neutral in terms of time/resource use (other than direct drug costs). Alongside use in CKD/heart failure patients, it is expected that use in acute life-threatening hyperkalaemia will reduce risk of sudden death associated with hyperkalaemia, and for patients on dialysis with resistant hyperkalaemia, this too will reduce risk of sudden death.	
7.	**Cost implications**	

	Treatment cost for acute hyperkalaemia is £42.71 per day for initial 3 days, then £7.12 to £14.24 per day in initial maintenance phase. There may well be a cost-saving in terms of emergency RRT for acute hyperkalaemia. For maintenance (i.e. CKD/HF use and dialysis patient use), the daily cost per patient is estimated to be around £7.12 / day. Based on data submitted to and published by SMC, it's estimated approximately 282 patients per year would be treated.
8.	**Form Prepared by***:* Jack Fairweather, Renal Consultant, UHM, NHSL
9.	**Endorsed by Professional Grouping***:* Name & signature of lead clinician Date