NHS Somerset

Shared Care Protocol
Sodium Zirconium Cyclosilicate (Lokelma®) for the treatment of persistent hyperkalaemia in adults

This shared care protocol (SCP) sets out details for the sharing of care for ***adult patients prescribed Sodium Zirconium Cyclosilicate (Lokelma®) for the treatment of persistent hyperkalaemia.***

It should be read in conjunction with the latest Summary of Products Characteristics (SmPC) available at http://www.medicines.org.uk/emc/

As outlined in NHS England Guidance 2018 (07573), 'Responsibility for Prescribing Between Primary & Secondary/Tertiary Care': When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the specialist and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

N.B. If the GP decides not to participate in shared care for a particular patient, they must inform the relevant specialist in writing, within 2 weeks of receipt of a request to share care.

Introduction

Sodium zirconium cyclosilicate (Lokelma®) is a non-absorbed cation-exchange compound that acts as a selective potassium binder in the gastro-intestinal tract. Sodium zirconium cyclosilicate is indicated for the treatment of hyperkalaemia in adult patients. NICE TA1148 recommends it as a treatment option for both emergency treatment of life-threatening hyperkalaemia and persistent hyperkalaemia in chronic kidney disease stage 3b to 5 or heart failure, if the patient fulfils the criteria set. The emergency treatment should be managed in an acute hospital setting and it is outside of the scope of this shared care protocol. Sodium zirconium cyclosilicate for the management of persistent hyperkalaemia initiated by a specialist can be continued under a shared care arrangement in line with NICE recommendations.

This document applies to adults aged 18 and over.

MHRA/CHMP advice:
Nil

For further information please click on the links below or visit:

- British National Formulary
- NICE TA1148 Sodium zirconium cyclosilicate for treating hyperkalaemia
- Summary of product characteristics – Lokelma®

Licensed indication and therapeutic use:

Sodium Zirconium Cyclosilicate is licensed for the treatment of hyperkalaemia in adult patients.

In line with NICE guidance, this shared care protocol covers the treatment of patients persistent hyperkalaemia in chronic kidney disease stage 3b to 5 or heart failure, if they

- have a confirmed serum potassium level of at least 5.5 mmol/L and
- because of hyperkalaemia, are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor and
- are not on dialysis

NICE recommends stopping sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable.

The initiation of the drug will take place in secondary care, by recommendation of specialist teams and under specialist advice and supervision.

Dose (posology & method of administration):

Correction phase: TO BE CARRIED OUT BY SECONDARY CARE
Not covered under this shared care protocol.

Maintenance phase:
When normokalaemia has been achieved, the minimal effective dose of sodium zirconium cyclosilicate to prevent recurrence of hyperkalaemia should be established. The recommended initiation dose is 5 g once daily, with possible titration up to a maximum of 10 g once daily or down to 5 g once every other day as needed to maintain a safe serum potassium level.

See ***Table 1: Dose titration & Adverse events/ Other management*** for further information on dose titration according to serum potassium levels.

Administration:
Manufacturer advice is to mix the contents of each 5g or 10g sachet of powder with approx. 45 mL of water and stir well. The powder will not dissolve, and the suspension should be taken while it is cloudy; if the powder settles it should be stirred again. To ensure the full contents of the sachet are taken, rinse the glass with more water if any particles remain.

For full details see SmPC

Contra-indications:

Hypersensitivity to the active substance.

For full details see SmPC

Cautions/ Special warnings and precautions:

- Serum potassium levels should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. renin-angiotensin-aldosterone system (RAAS) inhibitors or diuretics) and after the Sodium zirconium cyclosilicate dose is titrated.
- Hypokalaemia may be observed. Dose titration as described under maintenance posology may be required in such cases to prevent moderate to severe hypokalaemia. In patients with severe hypokalaemia, Sodium zirconium cyclosilicate should be discontinued, and the patient re-evaluated.
- Interaction with X-ray: sodium zirconium cyclosilicate may be opaque to X-rays, radiographers should keep this in mind if performing abdominal imaging.
- QT Prolongation: during correction of hyperkalaemia, a lengthening of the QT interval can be observed as the physiologic result of a decline in serum potassium concentration.
- Intestinal perforation: the risk for intestinal perforation is currently unknown. Since intestinal perforation has been reported with potassium binders including Sodium zirconium cyclosilicate, specific attention should be paid to signs and symptoms related to intestinal perforation.
- High sodium content: approximately 400 mg sodium per 5 g dose, equivalent to 20% of the WHO recommended maximum daily intake of 2 g sodium for an adult. This should be particularly considered for those on a low salt diet.

For full details see SmPC

Drug interactions:

As sodium zirconium cyclosilicate is not absorbed or metabolised by the body, there are no expected effects in its efficacy caused by other medicinal products.

Sodium zirconium cyclosilicate can temporarily increase gastric pH and may interfere with the absorption of medicinal products with clinically meaningful gastric pH dependent bioavailability.
In these cases, it should be administered at least 2 hours before or 2 hours after oral medicinal products.

For most other drugs that are not gastric pH dependent for absorption, the timing of taking the drug in relation to sodium zirconium cyclosilicate is not critical.

Examples of medicinal products with possible PH dependant interactions: azole antifungals (ketoconazole, itraconazole and posaconazole), anti-HIV agents (atazanavir, nelfinavir, indinavir, ritonavir, saquinavir, raltegravir, ledipasvir and rilpivirine) and tyrosine kinase inhibitors (erlotinib, dasatinib and nilotinib).

For full details see SmPC

Fertility, pregnancy & lactation:

Fertility: No human data on the effect of sodium zirconium cyclosilicate on fertility are available. In rats, there was no effect on fertility with sodium zirconium cyclosilicate treatment.

Pregnancy: There are no data from the use of sodium zirconium cyclosilicate in pregnant women. Avoid in pregnancy according to manufacturer's recommendations.

Breastfeeding: No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to sodium zirconium cyclosilicate is negligible. Can be used during breast-feeding.

See SmPC for full details

Adverse effects & management:

The most reported adverse reactions were hypokalaemia and oedema related events. Follow the instruction on Table 1 to adjust the doses to the potassium levels.

- If potassium levels <3.5 mmol/L - decrease dose or discontinue and monitor levels again in 1-2 weeks. Seek advice from the specialist team if necessary.
- If potassium levels > 6.5mmol/L – Refer for urgent treatment of acute hyperkalaemia.

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme https://yellowcard.mhra.gov.uk/

See ***Table 1: Dose titration & Adverse events/ Other management*** for the management of test results by primary care.

For full information and incidence of adverse effects see relevant SmPC

Advice to patients & carers:

- How to take the medication: The entire contents of the sachet should be emptied in a drinking glass containing approximately 45 ml of water and stirred well. The tasteless liquid should be drunk while still cloudy. The powder will not dissolve. If the powder settles, the liquid should be stirred again and taken. If needed, rinse the glass with more water to ensure that all of the content is taken.
- Leave a 2h gap between other medication when relevant (see interactions section)
- Do not stop taking sodium zirconium cyclosilicate without speaking to your GP or specialist. This is especially important when also taking RASS inhibitor therapy. Increases in serum potassium can occur as early as 2 days after stopping treatment.

- Inform medical practitioners if having an abdominal x-ray
- Advice on low potassium diet if appropriate.
- **The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:**
  - Hypersensitivity reactions to the active substance.
  - Signs of oedema
  - Severe diarrhoea or constipation
  - Signs of hypokalaemia or hyperkalaemia:
    - Weakness and fatigue, muscle cramps, aches and stiffness, heart palpitations, breathing difficulties, chest pain, nausea, or vomiting.

Shared Care Responsibilities

Secondary Care MDT/ Specialist team responsibilities:

- Assess the patient and provide diagnosis.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision, including information on side-effects and when to seek urgent medical attention (see also '**Advice to Patients & Carers'**).
- Provide an appropriate patient information leaflet on the individual medicine
- Ensure patient is counselled on how to take sachets, storage, potential side effects and advise that long term use has not been studied for more than a year.
- Counsel patient on the importance of adherence to sodium zirconium cyclosilicate, especially whilst also taking RASS inhibitor therapy. Increases in serum potassium can occur as early as 2 days after stopping treatment.
- Obtain and document consent.
- Assess the patient for contraindications, cautions and interactions
- Initiate and stabilise treatment with sodium zirconium cyclosilicate.
- Secondary care will review the patient every 1-2 weeks whilst initiating treatment and following any dose changes of other RAAS inhibitors therapy for the first three months.
- Once the specialist considers the patient's condition is stable or predictable, and treatment is optimised, a request can be made to the patient's GP to 'share' the patient's care. Primary care should continue to optimise RAAS inhibitors therapy if necessary, monitoring the potassium levels and adjusting the sodium zirconium cyclosilicate dose as indicated in ***Table 1: Dose titration & Adverse events/ Other management.***
- Potassium levels must be <5.5 mmol/litre before transferring patient to primary care.
- Notify the patient's GP that sodium zirconium cyclosilicate has been started. Communicate dose and established regime to GP. Confirm monitoring requirements, follow up arrangements and when to refer.
- Prescribe a 4-week supply when transferring patient to primary care and inform patient/carer of the arrangements for further prescriptions.

- If during a specialist team review for the original condition the need for treatment with sodium zirconium cyclosilicate, its ongoing dose or monitoring change, this should be communicated to primary care.
- Discontinuation of sodium zirconium cyclosilicate if RAAS inhibitors are no longer suitable.
- Provide ongoing advice to primary care where needed**.**
- Ensure that clear backup arrangements exist for GPs to obtain advice and support.
- All patients will remain under the ongoing care of a named consultant/specialist.
- The consultant/specialist will reassume prescribing responsibilities should any problem occur, that cannot be readily corrected in primary care.

General Practitioner responsibilities:

- Accept request to take on prescribing and monitoring of sodium zirconium cyclosilicate once the specialist considers a patient's condition is stable or predictable, treatment is optimised and the patient's potassium is stabilised between 3.5mmol/L and 5.5mmol/L, no sooner than 12 weeks after initiation.
- Reinforce educational points provided by the hospital. See also '*Advice to patients & carers'.*
- Primary care should adjust RAAS inhibitor dose as required to manage underlying condition e.g. CKD/HF, with view to optimising treatment.
    - Reduce the dose of RAAS inhibitors in persistent hyperkalaemia despite optimal doses of sodium zirconium cyclosilicate.
- Monitor U&Es and blood pressure 1-2 weeks after each RAAS inhibitor dose change.
- Adjust sodium zirconium cyclosilicate dose according to serum potassium results if required – ***Table 1: Dose titration & Adverse events/ Other management***
- Recheck U&Es within 1-2 weeks of each change in sodium zirconium cyclosilicate dose.
- Once patients are on a stable dose of RAAS inhibitors to manage the underlying condition and potassium binder to maintain a stable serum potassium level, monitor U&Es monthly for three months, then 3 monthly monitoring until stable to return the patient's usual monitoring schedule for RAAS inhibitor / underlying condition.
- Prescribe the sodium zirconium cyclosilicate at the dose recommended, from the agreed date.
- Remind patients of the importance of adherence to sodium zirconium cyclosilicate, especially whilst also taking RASS inhibitor therapy. Increases in serum potassium can occur as early as 2 days after stopping treatment.
- Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
- Seek specialist advice for an alternative treatment on a case-by-case basis in the event of an ongoing supply issue with sodium zirconium cyclosilicate that cannot be resolved locally.

Patient / carer responsibilities:

- After counselling, to be willing to take / administer prescribed medication as directed at home and attend regularly for monitoring and review appointments.
- Patients should not stop therapy without consulting their healthcare professional (increases in serum potassium may occur as early as 2 days after last dose of potassium binder). It is important to continue taking sodium zirconium cyclosilicate, especially whilst also taking RASS inhibitor therapy.
- Contact the General Practitioner if having issues with obtaining the medication, which could result in missing doses.
- To report any significant signs or symptoms relating to their condition, including side effects or concordance issues to the GP.
- Inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

'Table 1: Dose titration & Adverse events/ Other management

Primary care guide to Sodium Zirconium Cyclosilicate dose adjustment following out of reference range serum potassium result during maintenance treatment			
Result	**Action for Primary care**		
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance			
	Current dose		
	5g Alt days	**5g OD**	**10g OD**
Serum potassium (mmol/L)	**Recommended dose adjustment according to serum potassium result**		
3.0 – 3.4	**Discontinue**	Reduce to 5g Alt days	Reduce to 5g OD
3.5-5.4	No change Consider optimising RAASi therapy if applicable		
5.5-5.9	Increase to 5g OD	Increase to 10g OD	1. Look for and remove other contributors to hyperkalaemia* 2. Increase monitoring frequency if patient well and no AKI 3. Consider reducing RASSi dose **Refer to specialist**
6.0-6.5	Increase to 5g OD Advise to HOLD RASSi therapy and restart with the same dose once taking increased Sodium Zirconium Cyclosilicate dose	Increase to 10g OD Advise to HOLD RASSi therapy and restart with the same dose once taking increased Sodium Zirconium Cyclosilicate dose	1. Look for and remove other contributors to hyperkalaemia* 2. HOLD RASSi medication **Refer to specialist** or **Consider referral for hospital admission if acutely unwell**
>6.5	**Urgent referral for hospital admission under medicine**		
***Factors to consider in hyperkalaemia:**			
Artefactual Potassium supplements Use of salt substitutes e.g. 'LoSalt Potassium-sparing diuretics		Overdiuresis/hypovolaemia Non-selective beta-blockers Digoxin toxicity Trimethoprim/co-trimoxazole/NSAIDs	
Recheck U&Es within 1-2 weeks of each change in sodium zirconium cyclosilicate dose. Check U&Es and blood pressure 1-2 weeks after each RAAS inhibitor dose change.			
Discontinuing potassium binder • Discontinue if the patient develops a hypersensitivity reaction. • If RAAS inhibitor therapy is no longer indicated, review indication for ongoing use of Sodium Zirconium Cyclosilicate. • Seek advice from the relevant specialist team in secondary care, if necessary. (Cardiology/HF or Renal Team)			

Further support

- Contact specialist team via agreed channels.
- Prescribing & Medicines Management Team, NHS Somerset ICB
  Tel: 01935 384123 Email: somicb.medicinesmanagementteam@nhs.net

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Updated by:	Hels Bennett, Medicines Manager NHS Somerset ICB	
Reviewed by:	Duncan Whitehead, Consultant, Acute Medicine & Nephrology, SFT & Amy Burchell, Consultant Cardiologist, SFT	
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References

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- Lokelma 5 g powder for oral suspension - Summary of Product Characteristics (SmPC) [Online]. Available from: https://www.medicines.org.uk/emc/product/10059/smpc
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