

**North Central London**

**Joint Formulary Committee**

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| **Shared Care Guideline**  **Lokelma (Sodium Ziroconium Cyclosilicate) and Veltassa (Patiromer Calcium)**  **Treatment of hyperkalaemia** |

Dear Primary Care Prescriber.

The information in this shared care guideline has been developed in consultation with Primary Care, with agreement that shared care is appropriate.

Sharing of care assumes communication between the specialist, primary care prescriber and patient. The intention to share care should be explained to the patient by the specialist clinician when treatment is initiated. It is important that patients are consulted about treatment and are in agreement with it.

Further information on shared care, including out of area referrals, can be found in the NCL Interface Prescribing Guidance.

Shared Care Guideline

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| **Indication** | As per local formulary agreement*,* Lokelma and Veltassa are both potassium binders recommended for the treatment of adults with hyperkalaemia in line with [NICE TA599](https://www.nice.org.uk/guidance/ta599) and [NICE TA623](https://www.nice.org.uk/guidance/TA623) (i.e., for people with persistent hyperkalaemia and chronic kidney disease stage 3b to 5 or heart failure, if they have confirmed serum potassium level of atleast 6.0 mmol/litre, are not taking an optimised dosage of renin-angiotensin-aldosterone system (RAAS) inhibitor due to hyperkalaemia, and are not on dialysis).  Lokelma and Veltassa are used for other indications on the NCL Joint Formulary, but these are restricted to hospital only.  Treatment should be initiated by a clinician with expertise in the treatment of hyperkalaemia in the above patient groups, who will consider contraindications for [Lokelma](https://www.medicines.org.uk/emc/product/10074/smpc) and [Veltassa](https://www.medicines.org.uk/emc/product/779/smpc), as well as cautions for [Lokelma](https://bnf.nice.org.uk/drugs/sodium-zirconium-cyclosilicate/#cautions) and [Veltassa](https://bnf.nice.org.uk/drugs/patiromer-calcium/#cautions). | | | | |
| **Shared Care criteria** | Patients who are stabilised on Lokelma and Veltassa in line with [NICE TA599](https://www.nice.org.uk/guidance/ta599) and [NICE TA623](https://www.nice.org.uk/guidance/TA623), and have been monitored appropriately at baseline and after initiation of treatment with no problems identified during this period.  Once a patient has been stabilised on treatment for three months, a shared care arrangement with you will be requested. | | | | |
| **Dose** | **Initial stabilisation (by specialist team):**  The recommended starting dose of Lokelma is 10g, administered three times a day orally as a suspension in water.  The recommended starting dose of Veltassa is 8.4g once daily and the maximum dose is 25.2g. The dose can be increased or decreased after a minimum interval of 1 week based on serum potassium levels.  When normokalaemia is achieved, a maintenance regimen should be followed (see below).  **Maintenance dose:**  The table below outlines the action taken for when serum potassium levels are both in and out of range. It also highlights there is no dose adjustments for patients with either renal or hepatic impairment.   |  |  |  | | --- | --- | --- | | **Serum potassium**  **(**mmol/L) | **Action** | **Special considerations** | | <3.8 | Consider reducing dose of potassium binder (sodium zirconium by 5g/day or patiromer by 8.4g/day, if on lowest doses consider alternate days (unlicensed) or discontinue. Re check potassium within 2 weeks | **Renal impairment**: No dose adjustment required  **Hepatic impairment:** No dose adjustment required | | >3.8 and <5.1 | No change required | | >5.1 and <6.5 | Consider increasing dose of potassium binder (sodium zirconium by 5g/day to a maximum of 10g daily, patiromer by 8.4g/day to maximum of 25.2g daily. If at maximum dose, review other causes of hyperkalaemia and if needed consider down titration of RAASi therapy. | | ≥6.5 | Refer to hospital for repeat assessment and emergency treatment of acute hyperkalaemia. |   **Conditions requiring dose adjustment**  Further information about prescribing in elderly, children and pregnant women can be found for both [Lokelma](https://www.medicines.org.uk/emc/product/10074/smpc) and [Veltassa](https://www.medicines.org.uk/emc/product/779/smpc) by clicking on the links respectively.  **Missed doses**  If a patient misses a dose, they should be instructed to take the next dose at their normal time. The missed dose should not be taken with the next dose*.* | | | | |
| **Duration of treatment** | To continue taking until informed otherwise by specialist. | | | | |
| **Stopping criteria and treatment discontinuation** | Treatment should be discontinued immediately due to hypokalaemia (potassium equal to or less than 3.5mmol/L) or hypersensitivity to any of the ingredients found in either Lokelma or Veltassa. | | | | |
| **Baseline monitoring (by specialist)** | **Baseline monitoring:**   * Before initiating treatment, a baseline potassium should be measured. * For Veltassa, magnesium must also be monitored at least one month after initiation. | | | | |
| **Ongoing monitoring (by primary care clinician)** | **Test** | | **Frequency** | | **Action if out of range** |
| Serum potassium (Range: 3.5mmol/L to 6.5mmol/L).  Magnesium (Range: 0.7mmol/L to 1.2mmol/L)  Hypercalcaemia (Range: 2.2 mmol/L to 2.6mmol/L) | | 3-4 monthly (as advised by consultant)  6 monthly  Monthly for 2 months. If stable for 2 consecutive months; 6 monthly. | | Stop the medication and inform initial prescriber for advice.  If low, replace as per BNF guidance. Recheck after 2 weeks. If still low, refer to initial prescriber.  See section ‘Adverse effects and management’ below for management of hypercalcaemia. |
| **Follow up arrangements** | A specialist review in hospital will be undertaken 4-6 monthly to reduce burden in primary care.  The specialist will review the patient’s condition and communicate promptly with the GP when treatment is changed.  Patients with unstable potassium levels (consistently out of range) may require monitoring more frequent than 3-monthly. In these instances, prescribing and monitoring should be retained by the specialist. | | | | |
| **Adverse effects and management**    For a full list of adverse effects, please refer to the  BNF ([Lokelma](https://bnf.nice.org.uk/drugs/sodium-zirconium-cyclosilicate/" \l "side-effects) and [Veltassa](https://bnf.nice.org.uk/drugs/patiromer-calcium/#side-effects)) & SPC ([Lokelma](https://www.medicines.org.uk/emc/product/10074/smpc) and [Veltassa](https://www.medicines.org.uk/emc/product/779/smpc)).  Healthcare professionals are asked to report any suspected adverse reactions to the MHRA via the Yellow Card Scheme. | **Adverse effect** | **Frequency** | | **Action for GP** | |
| Hypokalaemia (potassium equal to or less than 3.5mmol/L)  Gastrointestinal upset  Nausea and Vomiting  Oedema (Lokelma specific)  Hypomagnesaemia (Veltassa specific)  Hypercalcaemia  (Corrected calcium more than 2.6mmol/L, note range may vary according to local laboratories – Veltassa specific) | Common  Common  Uncommon  Common  Common  Unknown | | Stop the medication and inform the initial prescriber.  Manage symptomatically, inform the initial prescriber if persistent.  Manage symptomatically, inform the initial prescriber if persistent.  Mostly self-limiting; may require adjustment of diuretic dose. If persistent, refer to initial prescriber.  This usually occurs during the initiation phase, before transfer to secondary care. Inform the initial prescriber if persistent.  Down titrate dose by 8.4g daily or discontinue Veltassa if causing persistent hypercalcaemia once all calcium supplements have been rationalised. Notify specialist as dose of RAASi therapy may also need to be adjusted. If hypercalcaemia continues then consider using alternative potassium binder (sodium zirconium). | |
| **Advice to patients and carers** | To inform specialist or GP of any other medication being taken, including over-the-counter products.  Report any adverse effects or warning symptoms as outlined in ‘Adverse effects and managements’ to the GP or specialist.  Lokelma – make up in 45ml of water and stir well. The powder will not dissolve. Administer azole antifungals, anti-HIV drugs and tyrosine kinase inhibitors 2 hours before or after sodium zirconium cyclosilicate.  Veltassa – make up in 40ml of water or apple juice and stir well. The powder will not dissolve. Take within an hour of initial suspension. Can be taken with or without food. Separate dose by at least 3 hours from other medications. Stored in the fridge but patients may store below 25℃ for up to 6 months. | | | | |
| **Resources and key references** | 1. NICE. Overview | Patiromer for treating hyperkalaemia | Guidance | NICE [Internet]. www.nice.org.uk. 2020 [cited 2024 Jan 9]. Available from: <https://www.nice.org.uk/guidance/ta623> 2. NICE. Overview | Sodium zirconium cyclosilicate for treating hyperkalaemia | Guidance | NICE [Internet]. www.nice.org.uk. 2019 [cited 2024 Jan 9]. Available from: <https://www.nice.org.uk/guidance/ta599/> 3. NICE. BNF [Internet]. NICE. 2023 [cited 2024 Jan 9]. Available from: <https://bnf.nice.org.uk/drugs/sodium-zirconium-cyclosilicate/#indications-and-dose> 4. NICE. BNF [Internet]. NICE. 2023. [cited 2024 Jan 9 Available from: <https://bnf.nice.org.uk/drugs/patiromer-calcium/> 5. Levien TL, Baker DE. Sodium Zirconium Cyclosilicate. Hospital Pharmacy [Internet]. 2018 Dec 14 [cited 2024 Jan 9];54(1):12–9. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6333952/> 6. Li L, Harrison SD, Cope MJ, Park C, Lee L, Salaymeh F, et al. Mechanism of Action and Pharmacology of Patiromer, a Nonabsorbed Cross-Linked Polymer That Lowers Serum Potassium Concentration in Patients With Hyperkalemia. Journal of Cardiovascular Pharmacology and Therapeutics [Internet]. 2016 July 8 [cited 2024 Jan 9];21(5):456–65. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4976659/> 7. AstraZeneca UK Limited. Lokelma 10 g powder for oral suspension - Summary of Product Characteristics (SmPC) - (emc) [Internet]. www.medicines.org.uk. 2023. Available from: <https://www.medicines.org.uk/emc/product/10074/smpc> 8. Vifor Fresenius Medical Care Renal Pharma UK Ltd. Veltassa (Patiromer) 8.4 g powder for oral suspension - Summary of Product Characteristics (SmPC) - (emc) [Internet]. www.medicines.org.uk. 2023. Available from: <https://www.medicines.org.uk/emc/product/779/smpc> 9. Guidance for the use of potassium binders in adults with hyperkalaemia and Heart Failure with reduced Ejection Fraction. North London Cardiac Operational Delivery Network. 2023. [cited 2024 Apr 19] | | | | |

Contact Details

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| Trust name:  **North Middlesex University Hospital NHS Trust**  Hospital Switchboard: 020 887 2000 | Specialist service contact details:  Consultant Physician and Nephrologist:  Dr Salman Sajid (Ext 2281)  Specialist Pharmacist: Ahmed Mohamed (Ext 3409) |
| **Royal Free London NHS Foundation Trust**  Hospital Switchboard: 020 3758 2000 | Consultant Cardiologist: Dr Ameet Bakhai  Via switchboard |
| **Whittington Hospital NHS Trust**  Hospital Switchboard: 020 7272 3070 | Consultant Nephrologist: Dr Mark Harber  Via switchboard |
| **Pharmacy Medicines Advice across NCL Trusts** | <https://nclhealthandcare.org.uk/16_contactdetails_MIHC/> |

**Document control**

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| Date | Version | Amendments |
| 18/09/2024 | 1.0 | New document developed by NMUH clinical team in liaison with the NCL ICB |

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| Groups / Individuals who have overseen the development of this guidance: | Dr Salman Sajid  Mr Ahmed Mohammed  NCL ICB Medicines Optimisation team |
| Groups which were consulted and have given approval: | NCL consultants and specialist pharmacists  NCL GPPA  NCL LMC  NCL Shared Care Group |
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| Equality impact assessment: | Low |
| NCL Shared Care Group Approval date: | 08/10/2024 |
| Review date: | 08/10/2027 |

Appendix 1: xxx transfer form: from [Trust] to GP practice

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| **Section A: to be completed by secondary care** *Send to practice*  *This document is to request the shared care pathway of your patient and comprises an agreement between the GP and named consultant. The patient will continue to be seen by the named consultant as regular follow up.* | | | | | | | | | |
| *Fix address label here (ensure NHS Number.on)* | | | | |  | Clinic stamp *or give details below* | | | |
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| Department |  | | | |  |  | | | |
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| Clinic phone |  | | | |  |  |  | | |
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| Consultant |  | | | |  | Email |  | | |
|  | | | | | | | | | |
| Indication for prescription |  | | | | | | | | |
|  | | | | | | | | | |
| Drug prescribed |  | | | | | | | | |
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| Date Drug started | |  | | Current dose | | | |  |  |
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| Relevant conditions |  | | | | | | | | |
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| Monitoring variations |  | | | | | | | | |
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| Date next blood test |  | | Next disease review due in | | | | |  | months’ time. |
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| **Section B: [Accept Shared Care] to be completed by practice**  *Send back* ***FAO referring consultant*** *above*  The above patient has been accepted into our monitoring service. | | | | |
| Practice date for next blood test | |  |  | Practice stamp |
|  | | |  |
| Signed /  Designation |  | |  |
| Date | | |  |

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| **Section B: [Reject Shared Care] to be completed by practice**  *Send back* ***FAO referring consultant*** *above*  The above patient has not been accepted into our monitoring service. | | | | |
| Reason | |  |  | Practice stamp |
|  | | |  |
| Signed /  Designation |  | |  |
| Date | | |  |