South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**154**
Intervention:	**Nephrotrans™ (sodium hydrogen carbonate) gastro-resistant capsules for the treatment and maintenance treatment against recurrence of metabolic acidosis in adults with chronic renal impairment** (Nephrotrans™ is an alkalinising agent)
Date of Decision:	**November 2024**
Date of Issue:	**December 2024**
Recommendation:	**Amber 1 – initiation in primary care on the recommendation of the specialist renal team**
Further Information	• Nephrotrans™ is a gastro-resistant soft capsule formulation of 500mg sodium bicarbonate (sodium hydrogen carbonate). • Nephrotrans™ gastro-resistant capsules are accepted for use in SEL as a **2nd line option** for the treatment and maintenance treatment against recurrence of metabolic acidosis in adults with chronic renal impairment under the following criteria: - Standard sodium bicarbonate preparations remain the first line treatment option. - Patients may be considered for Nephrotrans™ if they have experienced intolerable gastrointestinal (GI) side-effects from standard preparations of sodium bicarbonate after trialling for at least 4 weeks. - Minor GI side effects will not apply. Intolerable side-effects are defined as persistent side-effects (GI discomfort, nausea, flatulence, vomiting, reduced appetite) after trialling therapy with the standard release formulation for at least 4 weeks. • There should be a regular review of patients initiated on Nephrotrans™, for efficacy and tolerability. If patients continue to experience GI intolerability following a switch to Nephrotrans™, they should be switched back to standard preparations of sodium bicarbonate at an alternate dose. This will be guided by the specialist renal team. • The average daily dose required for patients can be achieved by taking 6-10 capsules of Nephrotrans™ daily. • Further information on Nephrotrans™ gastro-resistant capsules can be found in the summary of product characteristics (SPC).
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• The application estimates that ≤10% of patients requiring sodium bicarbonate in this setting will have intolerable side effects with the standard preparation, making them eligible for Nephrotrans™. This equates to approximately ≤ 140 patients per year in SEL. • The cost of Nephrotrans™ is ~ £650 per person per year which equates to a cost increase of ~£61,000 or (~£3,000 per 100,000 population) per year. Based on current prescribing data, the cost increase would be less than anticipated at approximately £27,000 or (£1,400 per 100,000 population) per year. • Switching patients to Nephrotrans™ could provide cost savings by reducing the number of patients requiring escalation to intravenous (IV) sodium bicarbonate replacement therapy and the associated service delivery impact. • The availability of Nephrotrans™ as a 2nd line option may also result in reduced hospital admissions for hyperkalaemia (high potassium levels). Additionally, patients may not require escalation to treatments for managing hyperkalaemia.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor use and submit usage data and audit reports upon request to the Committee.
	SEL Borough Medicines Teams: • Monitor ePACT2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed	References (from evidence evaluation)

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7. South East London Joint Medicines Formulary. Formulary Chapter 9: Nutrition and blood. Available online at: South East London Joint Medicines Formulary Formulary (Accessed : 27/09/2024)
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9. Martindale: The Complete Drug Reference. Bicarbonate. Available online Accessed via Medicines Complete (Accessed: 27/09/2024)
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13. Sorohan, B.M. et al. (2024) 'Sodium citrate versus sodium bicarbonate for metabolic acidosis in patients with chronic kidney disease: A randomized controlled trial', Medicine, 103(10). doi:10.1097/md.0000000000037475.
14. Medice UK LTD. Nephrotrans 500 mg gastro-resistant capsules, soft. SmPC. Available online at: https://www.medicines.org.uk/emc/product/15655/smpc#gref (Accessed: 27/09/2024)
15. Raphael, K.L. et al. (2019) 'A randomized trial comparing the safety, adherence, and pharmacodynamics profiles of two doses of sodium bicarbonate in CKD: The base pilot trial', Journal of the American Society of Nephrology, 31(1), pp. 161–174. doi:10.1681/asn.2019030287.
16. Hilton, N.P. et al. (2020) 'Enteric-coated sodium bicarbonate supplementation improves highintensity cycling performance in trained cyclists', European Journal of Applied Physiology, 120(7), pp. 1563–1573. doi:10.1007/s00421-020-04387-5.
17. 17. Zhou, N. et al. (2022) 'Acute enteric-coated sodium bicarbonate has negligible effect on anaerobic performance but affects metabolomics and attenuates the gastrointestinal response', Frontiers in Physiology, 13. doi:10.3389/fphys.2022.996381.
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NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS