South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**102**
Intervention:	**Naloxone nasal spray 1.8mg (Nyxoid™) for the immediate emergency treatment of known or suspected opioid overdose** (Naloxone is an opioid antagonist)
Date of Decision	**April 2019, updated June 2021 to extend time limited approval to June 2022, updated November 2023 following report on outcome data - time limit to the approval removed**
Date of Issue:	**May 2019, re-issued July 2021, re-issued January 2024**
Recommendation:	**RED –suitable for prescribing and supply by community addiction services only**
Further Information	• Naloxone nasal spray (Nyxoid™) is approved for use in South East London (SEL) within its licensed indication as an option for the immediate emergency treatment of known or suspected opioid overdose. Treatment is intended for use in adults and adolescents aged 14 years and over • Committee members acknowledged the complexities in service provision as addiction services are commissioned through local authorities, therefore service providers vary across SEL. • The local authorities in SEL who commission addiction services from the formulary applicant have provided their support for the application. • The addiction service must ensure appropriate education and training of service users/carers on the proper use of naloxone nasal spray. This includes use of the **educational risk minimisation materials**. • All prescribing and supply will be carried out by the addiction service. • The applicant confirmed that an original pack containing 2 single dose nasal spray containers will be issued to the service user. The applicant also confirmed that service users /carers are educated to call an ambulance immediately and it is therefore very unusual for a service user to use more than 1-2 doses. • **November 2023:** In May 2019 the Committee approved the inclusion of Nyxoid™ in the formulary for a time limited period to enable use to be piloted in selected services. The Committee requested a report summarising outcomes with the use of Nyxoid™ in this setting following the original formulary approval. Progress with the pilots was delayed due to external factors such as the COVID-19 pandemic. A report outlining the total number of patients initiated on treatment at two sites, the rationale for choosing Nyxoid™, and outcomes & safety data was presented in November 2023. The outcome data report found patient experience was positive. Service users are given a choice of treatment options, and many opt for Nyxoid™ as they find it easier to use. Staff within the services have found the intranasal formulation is more acceptable to external agencies and it is a preferred route with family members and non-clinical staff vs. intramuscular naloxone.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• There are currently just over 1,000 clients in the applicant's opioid substitution service and approximately 10% of these would be considered for the pilot. • The cost of Nyxoid™ is £27.50 (exc. VAT) for 2 spray containers vs. £18.00 for Prenoxad (naloxone 400 micrograms injection), which contains up to 5 doses. • It is difficult to predict the overall budget impact as it is not clear what the average number of doses required in an overdose might be and what the rate of further supply is, therefore the calculation below is unlikely to be accurate as several assumptions

	have been made. • Assumptions in calculation (based on ~100 service users receiving naloxone nasal spray over the course of the pilot): - Service users are given one pack of Nyxoid® (2 single dose sprays) on initiation or 1 Prenoxad®. - Over a 1 year period the mean rate of further supplies is 0.8 for Nyxoid™, and 0.4 for Prenoxad® (based on data from Madah-Amiri et al[2] where 277/433 (64%) clients used the device within an 18 month period, and Robertson et al[10] where re-administration requirements were 34% for intranasal and 18% for IM naloxone). • Use of naloxone nasal spray in the pilot would cost approximately £5K vs. £2.5K for intramuscular naloxone, i.e. an additional cost of ~£2,500. • This does not include service related savings, for example, better adherence from service users in carrying their naloxone.
Usage Monitoring & Impact Assessment	**Addiction services:** Monitor and audit usage of naloxone nasal spray (against criteria in this recommendation) and report back to the Committee upon request of the Committee
	SEL Borough Medicines Teams: • Monitor ePACT 2 data • Monitor exception reports from GPs if inappropriate transfer of prescribing to primary care is requested.
Evidence reviewed	**References (from evidence evaluation December 2018)** 1. Nyxoid – European Public Assessment Report. European Medicines Agency, September 2017. 2. Madah-Amiri D, Clausen T, Lobmaier P. Rapid widespread distribution of intranasal naloxone for overdose prevention. Drug and Alcohol Dependence 2017 173 p17-23 3. Nyxoid. Summary of Product Characteristics. Available here (accessed 30/03/2019). 4. Preventing fatal overdoses: a systematic review of the effectiveness of take-home naloxone. European Monitoring Centre for Drugs and Drug Addiction 2015. 5. Clark A et al. A systematic Review of community opioid overdose prevention and naloxone distribution programmes. J Addict Med 8 2014 DOI: 10.1097/ADM.0000000034 6. McDonald R, Lorch U, Woodward J et al. Pharmacokinetics of concentrated naloxone nasal spray for opioid overdose reversal: Phase I healthy volunteer study. Addition 2017 113 p484-493. 7. Kelly A et al. Randomised trial of intranasal versus intramuscular naloxone in pre-hospital treatment for suspected opioid overdose. Med J. Aust. 2005 182 p24-27 8. Kerr D, Kelly A, Dietze P et al. Randomised controlled trial comparing the effectiveness and safety of intranasal and intramuscular naloxone for the treatment of suspected heroin overdose. Addiction 2009 104 p2067-2074. 9. Sabzghabaee A, Eizadimood N, Yaraghi A et al. Naloxone therapy in opioid overdose patients: intranasal or intravenous? A randomised clinical trial. Arch Med Sci 2014 10 p309-314 10. Robertson T, Hendey G, Stroh G et al. Intranasal naloxone is a viable alternative to intravenous naloxone prehospital narcotic overdose. Perhospital Emerg Care 2009 13 p512-515 Doe-Simkins M, Walley A, Epstein A et al. Saved by the nose: Bystander administered intranasal naloxone hydrochloride for opioid overdose. Am J Public Health 2009 99 p788-791

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.**