South East London Area Prescribing 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**
Date of Issue:	**May 2019 (1 year time limited approval)**
Recommendation:	**RED – suitable for prescribing and supply by 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. • 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 Committee approved a pilot for the use of naloxone nasal spray, with particular focus on the following cohorts: - Service users who require carers to administer naloxone. - Service users who repeatedly fail to carry their intramuscular naloxone injection with them. • 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. • The applicant will report data from this pilot back to the Committee in 12 months outlining the following: (i) Total number of service users started on naloxone nasal spray by borough. This should include the proportion changed over from the intramuscular naloxone injection to nasal naloxone spray and the proportion of new patients (naloxone naïve). (ii) The rationale for naloxone nasal spray being chosen. (iii) The number of service users who are changed over to intramuscular injection and the reasons for this. (iv) Service user outcomes (including response, improvements in adherence to carrying naloxone, impact on the number of fatal opioid overdoses and any safety issues identified). (v) A summary of service user views/survey from the service user group. (vi) Potential cohorts of service users to be prioritised for receiving naloxone nasal spray. (vii) Any service activity related impact, including cost impact, arising from the implementation of naloxone nasal spray. • **This APC decision will be subject to review following submission of the 12 month report.** *Nyxoid is intended for immediate administration as emergency therapy for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression in both non-medical and healthcare settings. Nyxoid is indicated in adults and adolescents aged 14 years and over.
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 as outlined in this formulary recommendation and report back to the Committee in 12 months (data to be collated and presented no later than **July 2020**).
	CCGs: • Monitor ePACT 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 11. 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) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the APC website.

b) This Area Prescribing Committee 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**.