



Berkshire West Area Prescribing Committee Policy Statement

Drug Name	Nalmefene (Selincro®)
Indication under review	Reduction of alcohol consumption in adult patients with alcohol dependence
Policy No:	APC 089
Date of Issue, Date of reissue:	November 2014, May 2015
Review Date:	May 2018
Policy Statement: Nalmefene (Selincro®) is recommended for prescribing by GPs in primary care when recommended by local DAAT according to NICE TA and license criteria.	
Traffic Light Status	Amber
Key Points considered: <ul style="list-style-type: none"> The summary of product characteristics recommends nalmefene is prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption. This will be done with local DAAT (please refer to the prescribing guidance for this drug) NICE TA published November 2014 	
References: <ol style="list-style-type: none"> EPAR and Summary of Product Characteristics. Selincro, Lundbeck. Date last updated 25/02/2013. Available via http://www.ema.europa.eu Mann K et al. Extending the treatment options in alcohol dependence: A Randomised Controlled Study of As-Needed Nalmefene. <i>Biol Psychiatry</i>. http://dx.doi.org/10.1016/j.biopsych.20.10.020 (ESENSE1) Gual A, He Y, Torup L et al. A randomised, double blind, placebo-controlled efficacy study of nalmefene, as-needed use, in patients with alcohol dependence. <i>European Neuropsychopharmacology</i> 2013, http://dx.doi.org/10.1016/j.euroneuro.2013.02.006 (ESENSE 2) Van den Brink W. et al. Long-term efficacy, tolerability and safety of nalmefene as-needed in alcohol dependence: a randomised, double-blind, placebo controlled study. Presented at the 35th Annual RSA Scientific Meeting, San Francisco, California, USA, June 23-27, 2012. (SENSE) Van den Brink W, Aubin HJ, Bladstrom L, et al. ESENSE 1 - Randomised controlled 6-month study of as-needed nalmefene: subgroup analysis of alcohol dependent patients with high drinking risk level. Presented at the 21st European Congress of Psychiatry, Nice, France, 6-9 April 2013. Van den Brink W, Aubin HJ, Sorensen P et al. ESENSE 2 - Randomised controlled 6-month study of as-needed nalmefene: subgroup analysis of alcohol dependent patients with high drinking risk level. Presented at the 21st European Congress of Psychiatry, Nice, France, 6-9 April 2013. Van den Brink W, Sorensen P, Torup L et al. Long term efficacy of nalmefene as-needed in alcohol dependent patients with high drinking risk levels: results of a subgroup analysis. Presented at the 21st European Congress of Psychiatry, Nice, France, 6-9 April 2013. Van den Brink W, Aubin HJ, Bladstrom et al. Efficacy of as-needed nalmefene in alcohol-dependent patients with at least a high drinking risk level: results from a subgroup analysis of two randomised controlled 6-month studies. <i>Alcohol and Alcoholism</i>. Advanced Access published July 19, 2013;1-19 doi:10.1093/alcalc/agt061 NICE Clinical Guideline. Alcohol-use disorders: diagnosis, assessment and management of harmful drinking and alcohol dependence (CG115). February 2011. Nalmefene for managing alcohol dependence in primary and secondary care. Advanced planning information for the NHS. Lundbeck. Date of preparation 31st May 2012 and personal communication – January - October 2013. Nalmefene (Selincro) for the reduction of alcohol consumption – first line pharmacological therapy for alcohol dependence. Horizon Scanning Centre September 2012. NIHR HSC ID:3557. Available via http://www.hsc.nihr.ac.uk Nalmefene (Selincro) Scottish Medicines Consortium. SMC No 917/13 Issued 6 September 2013. Available via http://www.scottishmedicines.org/files/advice/nalmefene_selincro/FINAL_September_2013_website.pdf Rosner S, Hackle-Herrwerth A, Leucht S et al. Opioid antagonists for alcohol dependence. <i>Cochrane Database of Systematic Reviews</i> 2010, Issue 12. Art. No: CD001867. DOI: 10.1002/14651858.CD001867.pub3. Khanderia Suhas, editor. British National Formulary No 66. London: British Medical Association and the Royal Pharmaceutical Society of Great Britain; September 2013 - March 2014 	
Date taken to APC:	5 th November 2014
Date reconsidered at APC:	6 th May 2015
Date Ratified by MMC on Behalf of the Board:	12 th November 2014
Date ratified at APC (including final guidance on prescribing)	17 th June 2015

Berkshire West Area Prescribing Policies serve as a guide to clinicians. This does not overrule the clinical or budgetary responsibility of clinicians when considering treatment for individual patients.