South East London Area Prescribing Committee
Formulary recommendation

Reference	**101**
Intervention:	**Buvidal® (buprenorphine) prolonged-release solution for injection (weekly or monthly injection) for the treatment of opioid dependence** (Buprenorphine is an opioid medicine used to treat opioid dependence)
Date of Decision	**April 2019**
Date of Issue:	**May 2019 (1 year time limited approval)**
Recommendation:	**RED – suitable for administration by the addiction service only**
Further Information	• Buprenorphine prolonged release injection (Buvidal®) is approved for use in South East London (SEL) in line with its licensed indication* for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over. This approval covers both the weekly and monthly preparations of Buvidal®. • Committee members acknowledged the complexities in addiction service provision as these 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 Buvidal®, with particular focus on the following cohort: - Service users those who find the limitations of daily supervised use challenging. For example, those who fail to complete treatment as they do not turn up to daily appointments. • Administration of Buvidal® is **restricted to healthcare professionals**. Take-home use or self-administration of the product by patients is **not allowed**. • As buprenorphine is a Schedule 3 (CD No Register) controlled drug, the service must comply with regulations for ordering, storing and supplying controlled drugs. • 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 Buvidal® by borough and the split between weekly and monthly injection. The data should include the proportion changed over from oral buprenoprphine to the prolonged release injection and the proportion of new patients (buprenorphine naïve). (ii) The rationale for buprenorphine prolonged release injection being chosen for the service user. (iii) The number of service users who are changed from Buvidal® injection to oral buprenorphine during the course of the pilot and the reasons for this. (iv) Service user outcomes (including reduction in opioid use, retention of service users [improvements in clinic attendance] 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 Buvidal® following the pilot. (vii) Any service activity related impact, including cost impact or savings, arising from the use of Buvidal®. • **This APC decision will be subject to review following submission of the 12 month report.** *Buvidal® (all preparations) is licensed for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.
Shared Care/ Transfer of care required:	N/A

Cost Impact for agreed patient group	• The applicant confirmed that the cost of prescribing and administration is included in their contracts with local authority commissioners. • Including pharmacy activity fees, the cost of Buvidal® is £230 per month for weekly treatment, and £241 per month for 4 weekly injections. The cost of sublingual buprenorphine ranges between £190 and £353 per month, and Buvidal® appears cheaper for sublingual doses >12 mg daily. Therefore the use of Buvidal® is likely to be cost neutral. • This does not include savings from reduced service activity, which are more difficult to estimate but will be informed through the pilot.
Usage Monitoring & Impact Assessment	**Addiction services:** • Monitor and audit usage of Buvidal® 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/administration in primary care is requested.
Evidence reviewed	**References (from evidence evaluation December 2018)** 1. Opioid dependence: buprenorphine prolonged-release injection (Buvidal®). NICE Evidence Summary 19 (Feb 2019). 2. Methadone and buprenorphine for the management of opioid dependence. National Institute for Health and Care Excellence Technology Appraisal 114 (January 2007) 3. Buvidal® (buprenorphine prolonged release injection) Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/9706/smpc (accessed 28/03/2019) 4. Lofwall M, Walsh S, Nunes E et al. Weekly and Monthly Subcutaneous Buprenorphine Depot Formulations vs Daily Sublingual Buprenorphine With Naloxone for Treatment of Opioid Use Disorder. A Randomised Clinical Trial. JAMA Internal Medicine 2018 178 (6) p764-773

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**.