South East London Integrated Medicines Optimisation Committee
(formerly the Area Prescribing Committee)
Position Statement

Reference:	**PS-027**
Intervention:	**Preferred choice of methylphenidate modified-release (MR) tablet brand for the treatment of attention deficit hyperactivity disorder (ADHD) in children and in adults (off-label) and for other off-label indications of narcolepsy and idiopathic hypersomnia (as noted in the SEL Joint Medicines formulary)** **NOTE:** Methylphenidate is categorised as **AMBER 3** within the SEL Joint Medicines Formulary, therefore use of the relevant shared care guidelines will apply.
Date of Decision:	**July 2020**
Date of Issue:	**September 2020**
Recommendation:	The following recommendations are for methylphenidate **MR TABLETS which are bioequivalent to Concerta® XL** only (this excludes Ritalin-SR® tablets). · Following discussions with ADHD and sleep centre specialists, in SEL the preferred brands of methylphenidate modified release (MR) preparations are: - Delmosart® prolonged release tablets and - Xenidate® XL tablets · **New patients** should be initiated on either Delmosart® prolonged-release tablets or Xenidate® XL Prescribers must specify the **brand** of methylphenidate MR to be dispensed. **Existing patients currently prescribed Concerta® XL** · Patients currently prescribed a stable dose of Concerta® XL must only be switched to either Delmosart® prolonged-release tablets or Xenidate® XL once 6 months has passed since initiation of treatment with Concerta® XL. All patients must be reviewed one month after switching. · If the patient has problems with the switch after one month, i.e. ADHD control worsens, then the other branded generic can be tried (i.e. if already switched to Delmosart® prolonged-release tablets then Xenidate® XL should be tried or vice versa). · If a patient still finds that their ADHD is not as well controlled as it was previously on Concerta® XL then they can be switched back to Concerta® XL. · Concerta® XL is reserved as a 3rd line option for patients who have failed to respond to **both** Delmosart® prolonged-release tablets and Xenidate® XL. · Patients currently prescribed Matoride® XL or Xaggitin® XL tablets can remain on these preparations and do not need to be switched. · Patients currently prescribed Ritalin-SR® tablets should remain on these tablets as these are not bioequivalent to Concerta® XL.
Further Information:	· There are several brands of methylphenidate MR tablets currently available, including Concerta® XL tablets, Xaggitin® XL tablets, Delmosart® prolonged-release tablets, Xenidate® XL tablets and Matoride® XL tablets. · All are licensed for ADHD in children over 6 years of age and adolescents when remedial measures alone prove insufficient. Initiation in adults is outside of the product licence. Methylphenidate is also used off-label to treat narcolepsy and idiopathic hypersomnia in line with SEL APC guidance. · Delmosart® prolonged-release tablets, Xenidate® XL tablets, Xaggitin® XL tablets and Matoride® XL tablets have been granted marketing authorisation based on their bioequivalence to Concerta® XL tablets. · A review completed by the London Medicines Information Service looked at the bioequivalence studies for each of the above preparations (not Ritalin-SR® tablets)

Further Information continued:	vs. Concerta® XL and concluded that these branded generics have satisfied the criteria for equivalent release profile to Concerta® XL tablets. The paper suggests that it would seem appropriate for these branded generics to be considered as alternatives to Concerta® XL when initiation of Concerta® XL is appropriate. · NICE do not make any recommendations on the prescribing of specific brands but state that, "if there is a choice of one or more appropriate drug, the product with the lowest cost should be prescribed" (see 'cost impact for agreed patient group' below). · Matoride® XL tablets are not available in a 27mg strength unlike the other branded generics and have, therefore, not been considered for use in South East London. Xaggitin® XL has been dispensed for only a very small number of patients in South East London compared with Delmosart® and Xenidate® XL tablets therefore this preparation has also been excluded. · Two preferred branded generic options have been recommended as the companies that manufacture branded generics can be relatively small with limited manufacturing capacity. The impact of including one branded generic in the formulary could create a large demand for the product over a very short period of time, therefore, supply could potentially be limited. · Both Delmosart® prolonged-release tablets and Xenidate® XL are similar in price. · There has been some anecdotal evidence which states that switching to a branded generic version of methylphenidate MR from Concerta® XL has led to destabilisation of patients with ADHD. Particularly, the new product wearing off later in the day being the most commonly reported issue. This is also a reason why more than one brand/branded generic preparation of methylphenidate MR should be available. · A straight switch can be made from Concerta® XL to the equivalent dose of either Delmosart® prolonged-release tablets or Xenidate® XL. There is no requirement for dose adjustment or re-titration of the dose when switching. · Patient information leaflets have been produced to aid the switch in primary care.
Cost Impact for agreed patient group	Concerta® XL tablets are approximately twice the cost of the branded generic formulations. If 100% of patients in SEL were to switch from Concerta® XL to either Delmosart® modified-release tablets or Xenidate® XL tablets, the annual cost saving is estimated to be around £422,424.
Usage Monitoring & Impact Assessment	**Mental Health and Acute Trusts** · Monitor use of the preferred MR methylphenidate brands and audit upon request for reporting back to the APC. **SEL CCG Boroughs** · Monitor prescribing trends via Epact2 · Exception report if inappropriate requests to prescribe are made to primary care.
Evidence reviewed:	1. NHS Specialist Pharmacy Service - London Medicines Information Service, Bradley, M and Radia, H. Extended-release methylphenidate – a review of the pharmacokinetic profiles of available products, 2018; Available here [Last accessed 03/02/2020] 2. Joint Formulary Committee (2020) *British National Formulary*. Available at: https://bnf.nice.org.uk/ [Last accessed 03/02/2020] 3. PrescQIPP Community Interest Company. Branded Generic Drug Saving; Bulletin 141. May 2016; https://www.prescqipp.info/media/1130/b141-branded-generic-drugs-22.pdf [Last accessed

NOTES:

a) Area Prescribing Committee recommendations, position statements and minutes are available publicly via the APC website.

b) This Area Prescribing Committee position statement has been made on the cost effectiveness, patient outcome and safety data available at the time. The position statement 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.