Bedfordshire, Luton and Milton Keynes Area Prescribing Committee – Formulary Subgroup meeting
Meeting Notes – February 2024

Date: 6th February 2024
Time: 13.00 - 15.00pm
Venue: Microsoft Teams

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

Name	Initial	Role	Present	Absent
Fiona Garnett	FG	Committee Chair	✓	
Taiya Large	TL	Professional Secretary/Formulary & Medication Safety Pharmacist, NHS BLMK ICB	✓	
Janet Corbett	JCo	Pharmacy Programme Manager MKUH		✓
Saema Arain	SA	ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton)		✓
Anshu Rayan	AR	CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes)		✓
Dr Mya Aye	MA	Medical Representative, Milton Keynes University Hospital		✓
Dr Eleanor Tyagi	ET	Medical Representative, Milton Keynes University Hospital		✓
Carole Jellicoe	CJ	Nurse and Non Medical Prescribing Representative (Secondary Care)		✓
Nikki Woodhall	NW	Formulary Lead Pharmacy Technician, BLMK ICB		✓
Dr Kate Randall	KR	GP Representative, Bedfordshire and Luton	✓	
Dr Jenny Wilson	JWi	GP Representative, Bedfordshire and Luton	✓	
Reginald Akaruese	RA	CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes)	✓	
Mojisola Adebajo	MA	Place Based Lead Pharmacist BLMK ICB	✓	
Matt Davies	MD	Place Based Lead Pharmacist BLCK ICB	✓	
Alex Hill	AH	Community Pharmacy Representative	✓	

Dr Dush Mital	DM	Medical Representative, Milton Keynes University Hospital NHS Trust	✓	
Yolanda Abunga	YA	Pharmacist Representative, Cambridgeshire Community Health Services	✓	
Marian Chan	MC	Consultant, Bedfordshire Hospitals NHS Foundation Trust	✓	
Naomi Currie	NC	Place Based Lead Pharmacist BLMK ICB	✓	
Anne Graeff	AG	Commissioning Lead Pharmacist BLMK ICB	✓	
Joy Mooring	JM	Primary Care Specialist Pharmacy Technician, BLMK ICB	✓	
Samantha Golton	SG		✓	
Dona Wingfield	DW	Medicines Use and Quality Manager, Bedfordshire Hospitals NHS Foundation Trust		✓
Anila Anwar	AA	Governance and Policies Pharmacist Bedfordshire Hospitals NHS Foundation Trust	✓	
Iffah Salim	IS	Interim Tower Hamlets Lead Pharmacist, ELFT BLMK ICB		✓
Nicholas Beason	NB	Procurement technician MKUH	✓	
Candy Chow	CC	Commissioning Lead Pharmacist BLMK ICB	✓	
Sandra McGroaty	SMc	Commissioning Pharmacist, BLMK ICB		✓
Jonathan Walter	JWa	Milton Keynes GP representative		✓
Dupe Fagbenro	DF	Deputy Chief Pharmacist (Luton and Bedfordshire) East London NHS Foundation Trust	✓	
Alisha Gandhi	AGa		✓	
Samina	SH		✓	
Jane Stanger	JS		✓	
Sarah Wocka	SW		✓	

Summary of acronyms used in the document

Acronym	Explanation
MKF	Milton Keynes Formulary
B&LF	Bedfordshire and Luton Formulary
FSG	Formulary subgroup
SS/Orx	Scriptswitch/Optimise GP messages
SCG	Shared care guidance

<table>
<tr><th>No</th><th>Agenda Item</th></tr>
<tr><td>1.</td><td>Welcome, Introductions and Apologies

The chair welcomed everyone to the meeting.

The meeting was confirmed as quorate.</td></tr>
<tr><td>2.</td><td>Declarations of Interest

Annual written declarations of interests up to date.

Members were invited to declare any conflicts of interest relating to matters on the Agenda, none declared.</td></tr>
<tr><td>3.</td><td>Minutes of the previous meeting

The November 2023 FSG meeting notes were approved as accurate.</td></tr>
<tr><td>4.</td><td>Action Log

Actions were noted in accordance with the action log:

<table>
<tr><th>Item</th><th>Title</th><th>Action</th><th>Update</th></tr>
<tr><td>1</td><td>Dementia SCG</td><td>Expand for use BLMK wide</td><td>On agenda for approval</td></tr>
<tr><td>2</td><td>Gepretix</td><td>Deploy Optimise Rx messages for switching for new patients (represents 30% cost saving over other available products)</td><td>Actioned – To close</td></tr>
<tr><td>3</td><td>Anticholinergic liquids</td><td>The place of liquid preparations were also discussed in more detail, noting that if the patch is approved for swallowing difficulties then there may be no place for liquids. Possible use in children and care homes / where patches may damage the skin. Further investigation into the place of liquids and re-visit. Action RP: To feedback rationale for use of liquids over patches in elderly patients (NB: patches are not listed on prescribing system at the Trust). To confirm also with paediatrics regarding possible switch to solifenacin liquid (cost-effective) vs oxybutynin liquid. Small numbers of patients overall.</td><td>Open – TL to continue to review.</td></tr>
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	Note regarding Gepretix 100mg: There is currently a Class 4 defect alert on Gepretix, relating to an inaccuracy in the patient information leaflet. The product is not being recalled therefore stocks should not be affected.
5.	**Items for consideration**
5.1	**Glycopyrronium 1mg & 2mg tablets (Assicco brand)** • Assicco is licensed for symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. Glycopyrronium Bromide liquid preparation is currently on both formularies. However, when ePACT data was reviewed a significant proportion of Tablets have been prescribed in primary care but is not on the formulary (19% of total oral glycopyrronium). • Whilst looking at cost effective switch options for BLMK, Assicco was considered as a cost-effective brand of Glycopyrronium tablets – small patient numbers but significant saving potential. • Therefore, the application is to consider adding tablets on to Beds/Luton & MK Formularies as a cost-effective formulation alternative to liquid preparations in line with current use, recommending Assicco brand as 1st line tablet option. • It should be noted that use in adults is not licensed however a review of data for BLMK suggests adult prescribing for both the licensed indication (sialorrhea) and also for hyperhidrosis. Hyperhidrosis is not part of the pathway as agreed in April 2022, therefore alongside the application it is proposed that Optimise Rx messages are constructed and deployed to clarify the stance i.e. prescribing for hyperhidrosis is not supported. • Active switching of those on generic tablets to Assicco is required to realise the cost savings. • **Proposal: Add Assicco as the preferred tablet option for sialorrhea in children and adolescents (licensed) and also for the same indication in adults (off-label). Use for hyperhidrosis is not supported. Traffic light – SpA, in line with Sialanar solution.** • The proposal was approved.
5.2	**Freestyle Libre 3 (FSL3)** FSL3 was previously approved for use in the Continuous Glucose Monitoring guidance via APC, however due to a change in the route of supply the device (FSL3 is now in the Drug Tariff and available to prescribe on FP10) has been brought to FSG to agree the best mechanism for prescribing and by whom. Recently, FSL2 software was upgraded to a real time continuous glucose monitoring system, similar to FSL3. This is a highly desirable feature for the device operation. Other advantages of FSL3 are less pronounced and include: • Sensor is lighter and smaller vs FSL2 – this may be preferable for children as the sensor is less cumbersome • Stakeholders in paediatrics preferred using FSL3 due to the ability for remote sharing of data with parents. (NB: This is also possible with FSL2). • FSL3 is slightly more accurate in readings: A mean absolute relative difference (MARD) is 9.2% for FSL2 and 7.8% for FSL3 overall. • FSL3 carries a wider transmitter range of 10 meters vs 6 meters for FSL2. • FSL3 has a sensor memory of 14 days vs 8 hours for FSL2. • As a negative, FSL3 carries a higher cost per patient vs FSL2 of £182 per patient.

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	BLMK ICB have 3000 people on FSL2, if all were to move to FSL3 this would represent an additional cost pressure of £546,000 in total per annum. BLMK ICB also currently have a rebate in operation for FSL2 which is volume based – if patients were switched en masse to FSL3, the rebate would be voided which would also represent an additional cost pressure to the ICB. Specialists also voiced a lack of support for switching all patients currently on FSL2 over to FSL3, stating they would rather use monies to expand use of CGM to all patients with type 1 diabetes. There is currently a historical difference in contractual arrangements for payment between Bedfordshire Hospitals NHS Foundation Trust (BHFT) and Milton Keynes University Hospital (MKUH), the latter being in block for these devices. FSL3 is currently supplied by the Trusts (Red Formulary status) – option 1 would retain the status quo but would not realise a saving on VAT (approx. £66k p.a.) and retains the increased burden in relation to ordering. This option is recognised as being less convenient for patients and usage figures are not available via EPACT if option 1 is chosen. Option 1 would however prevent unnecessary upgrade of FSL2 to FSL3 (high cost pressure). All subsequent options allow prescribing in Primary Care under SpA – specialist advised formulary status, with a difference in the eligibility criteria for each option: Option 2 – Existing patients on FSL3 transfer to FP10 prescribing via GP, new initiations are restricted to those patients with Type 1 diabetes (T1DM) using a Hybrid Closed Loop pump system. Option 2a – Due to the difference in contracting arrangements, this option could be restricted to Bedfordshire hospitals NHS Foundation Trust (BHFT) only. (Less desirable as results in inequity for patient access). Option 3 – As above but eligibility expanded to include allowing diabetic patients under 20 years of age to use FSL3 as a standalone device. Option 3a would be to again restrict this to BHFT for the above mentioned reasons. Options 2&3 would also prevent unnecessary upgrade from FSL2 to FSL3. If option 2 or 3 were selected however, a new method of payment for MKUH would need to be agreed as monies cannot be extracted from the block contract. Option 4 – As above for existing patients, plus FSL3 becomes an option for all new patients and those on FSL2 have the option to move to FSL3. This option carries the highest cost pressure and the benefits of upgrade are not felt to be sufficient enough to justify this spend. This option would also need executive financial sign off and a business case. Feedback from stakeholders were unanimous to support option 2 or 3. The group agreed Option 3a temporarily, with further discussions with MKUH around financials to enable Option 3 to be realised. Post-meeting note: AH to explore with Abbott how the ordering cap for community pharmacies of 6 sensors may be increased if the use of FSL3 was expanded within BLMK. Response as below:  PMR REPORT - C & H (Barton) Ltd.pdf

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5.3	**Dementia Shared Care Guidance** The dementia SCG was brought to the last meeting of the formulary subgroup in November but was only applicable for Bedfordshire and Luton. At the last meeting, it was indicated that this may be able to be extended to include Milton Keynes. The committee is therefore asked to review the SCG with a view to adopting it for use across the whole of BLMK. The SCG comprises information to support the initial sharing of care between the specialist and the GP/primary care prescriber, and the subsequent transfer of care. Practices can refer back to the specialist service at any time if they need advice about anti-dementia medications or there has been a deterioration in cognitive function. Previously there has not been shared care agreed in MK and therefore this will also require a change in the formulary traffic light status from SpA to Amber SCG, but this change will provide additional support and guidance for primary care clinicians. The SCG was approved for use. Designation on MKUH Formulary to be updated from SpA to SCG.
5.4	**Azathioprine 75mg and 100mg tablets** Two new strengths of tablet have recently been launched and carry a significantly higher cost (~£30-40 for 100 vs ~£2-4 for 100 of the 25mg and 50mg currently on Formulary). The group acknowledged the potential benefit of reduced pill burden for patients on higher doses was not outweighed by the risks associated with dosing error e.g. if higher strength was prescribed the patient may inadvertently take the same number of tablets they are used to leading to overdose. Pharmacy colleagues also raised concerns about picking error, for which the risk increases where more strengths are available. Azathioprine was felt to be in a similar category of risk to methotrexate, therefore limiting of available strengths will mitigate against dosing errors. The proposal to designate 75mg and 100mg strengths “DNP” was approved.
5.5	**Generic apixaban** The patent holder for apixaban, Bristol Myers Squibb (BMS), incorrectly filed the patent extension for apixaban which has led to the early and unexpected introduction of generic apixaban. The introduction of generic apixaban was legally challenged by BMS, and rejected by the Court of Appeal, BMS appealed the decision, and sought permission to take the legal case to the Supreme Court. In October 2023 the appeal to take the legal case to the Supreme Court was declined. This means that there is no further barrier to the supply of generic apixaban. Based on the current pricing and estimated patient numbers the predicated saving based on current prescribing of the apixaban price drop is £4.7M per annum for BLMK ICB. Active switching from edoxaban to apixaban is not desirable due to the workload burden on GPs and the presence of a market share dependent rebate on edoxaban, which if voided would result in a significant additional cost pressure for the ICB. Concerns have also been raised around the dosing change from once daily with edoxaban to twice daily with apixiaban, which may not be favourable to patients. The group noted there is also legal challenge ongoing with rivaroxaban which may also lose patented status going forward. MD recommended utilisation of the new DOAC dashboard on Eclipse to identify those who may be clinically appropriate for a switch e.g. those on warfarin with poor time in range of INR.

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	Recommendations: - Due to the completion of the legal challenge and the significant unforeseen price reduction of apixaban and change in NHS England guidance: • Change the formulary to have generic apixaban first line within its licensed indications as the preferred DOAC for new patients where clinically appropriate. • All DOACs remain an option on the BLMK formulary in line with the NICE TAs. • Current patients to remain on their existing DOAC until further guidance is received unless it is clinically appropriate to change (no active switching).
5.6	**Semaglutide tablets (Rybelsus)** Following publication of the National Patient Safety Alert (NatPSA) relating to shortages of GLP-1 RAs, the medicines optimisation team is proposing a temporary change to the joint first line GLP-1 RA options in both formularies during the period of the GLP-1 RA national shortage. Rybelsus® will be offered as first-line option for new initiations for those meeting criteria in NICE NG28 and the other injectable GLP-1 RAs licensed for T2DM in adults will be second line options. The continuation criteria for all GLP-1 RA in line with NICE NG28 will still apply. Supplies of Ozempic and Trulicity are not as critical as for Victoza, at the current time these patients do not require switching away from these two preparations. Across BLMK, there are currently 590 patients identified on SystmOne who have Victoza® (liraglutide) on repeat and 12 patients identified with Byetta® (exenatide) on repeat prescription. As per the NatPSA these patients will need to be reviewed and switched to Rybelsus®. NB: Byetta is being discontinued by March 2024. If any of these patients are not suitable for Rybelsus, advice and guidance should be sought from the patient's specialist. Where treatment goals have not been achieved, GLP-1 RA should be discontinued, and another glycaemic agent should be prescribed. The proposal was accepted. MA to develop a short guide for how to switch patients from an injectable GLP-1 RA to Rybelsus to support prescribers. MA/TL to work together to produce wording for the Formulary to support prescribers.
5.7	**Nutriprem Human Breast Milk Fortifier** Nutriprem human milk fortifier is a Food for Special Medical Purposes for use under medical supervision for the dietary management of preterm and low birth weight infants*. It is added to mother's own expressed breast milk or to donor breast milk and should be used under the supervision of a neonatologist, dietitian or medical clinician. **Application is for preterm infant use only.* The course is usually short and ends somewhere between 48 and 52 weeks gestation (6-8 weeks past term due date). Nutriprem human milk fortifier is now ACBS approved and available on FP10 prescription from the 1st December 2023. The MKUH neonatology team would like the prescribing of the product continued by primary care on discharge from hospital in babies where there is a clinical need.

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	Estimated approx. 8 patients per annum from MKUH, representing a cost pressure in the region of £4000 per annum to primary care. BHFT confirmed in meeting that it is also a product in use on the neonatal unit there. SW/TL to obtain usage figures and BHFT model for supply (if any) on discharge. GP representatives raised concerns about the specialist nature of the product and also the fact that GPs tend not to see an infant so early on and therefore were not best placed to supply the rest of the sachets following discharge. Support for the products use was however received. AH noted that it wasn't available to order in community – to investigate and feedback. The application received support for use however approval for GP prescribing was not supported. FG/TL to work with SW and JS to explore viability of alternative HCPs e.g. Health Visitors, who may be better placed to assess and prescribe for these infants. TL/SW to obtain usage figures from BHFT and review cost-pressure data. Post-meeting note: AH confirmed ordering details on Alliance as follows: Drug Name / PIP / EAN: 8062564 Product: CG IMF POWD HMF (CG IMF POWD HMF) Pack of 50G (4) — EAN:8718117111459 PIP: 8062564 — Supplier: NUTRICIA LTD — Price: £42.50 Considerations- • Ordering system forces 4 boxes at a time – possible wastage if patient numbers low and courses are short following discharge. • An old product (2.2g size) is showing on SystmOne as being available to prescribe. The manufacturer confirms this has been discontinued. • The product name on the ordering system is difficult to find – pharmacies may not be able to locate to order.
5.8	**Biosimilar Insulins** Insulin glargine is a long-acting insulin analogue with the originator brand Lantus widely prescribed across BLMK. Biosimilar insulins have the same biological substance to the reference medicine but with a degree of natural variability. There are currently two biosimilar brands of insulin glargine 100 units/mL available: Abasaglar® and Semglee®. Recent information on possible supply chain disruptions with Lantus highlighted need to align Formulary designations in case of future stock issues – insulin glargine biosimilars can support uplift in demand. ➢ MK Formulary - Lantus and insulin glargine biosimilars (Abasaglar® and Semglee®) are **SpA.** ➢ Beds/Luton Formulary- Lantus is **Green** and both insulin glargine biosimilars are **non-formulary** Committee to consider addition of Abasaglar and Semglee to Beds/Luton Formulary to align both Formularies - 2nd Line option to Lantus. Also, all insulin glargine formulations to be designated Green on both Formularies.

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	➢ For new initiations, insulin glargine biosimilar may be prescribed with the most cost-effective brand (Semglee) to be considered. ➢ Prescribing should be by brand to reduce risk of mis-selection or picking error - all the insulin glargine pre-filled pens all look very different. ➢ No switching of existing patients is being recommended, except in the case of a supply shortage of Lantus, but if patients are switched between brands of insulin glargine dose adjustment may be needed. The three brands were all noted to be visually different and therefore pharmacy and on-ward picking errors should not be a concern. Recommendations: • Addition of Abasaglar and Semglee to Beds/Luton Formulary to align both Formularies - 2nd Line option to Lantus. • All insulin glargine formulations to be designated Green on both Formularies. NB: Toujeo, although an insulin glargine is not bioequivalent to Lantus and is therefore out of scope of the application (no change to be made to Toujeo)
6	**Minor amendments log** Nil comments received – changes approved. 6 Minor amendments log for Feb 24 FSG MI
AOB	New product – Cytisine 1.5mg tablets for smoking cessation. Nicotine receptor partial agonist, complete treatment course of 25 days = £115. Propose: Non-Formulary pending review and discussion with Public Health. Approved. DF – ELFT contract with Formulary complete is ending – currently collaborating with NEL to explore the use of NetFormulary going forward. Meeting dates for 2024 are available on BLMK ICB Website – Formulary Page https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/