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

Date: 3rd September 2024
Time: 12.30 - 14.00pm
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	✓	
Samina Hassanali	SH	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	✓	
Anne Graeff	AG	Commissioning Lead Pharmacist BLMK ICB	✓	
Joy Mooring	JM	Primary Care Specialist Pharmacy Technician, BLMK ICB	✓	
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	✓	
Maggie Winter	MW	Milton Keynes GP representative		✓
Dupe Fagbenro	DF	Deputy Chief Pharmacist (Luton and Bedfordshire) East London NHS Foundation Trust		✓
Qiratulain Khan	QK	Lead Pharmacist Medicines Information and Formulary	✓	
Amjid Hussain	AHu	Lead for the Community Mental Health Services across Bedfordshire	✓	
Katy Savage	KS	Lead Dietitian for Food First & Prescribing Support	✓	

Summary of acronyms used in the document

Acronym	Explanation
MKF	Milton Keynes Formulary
B&LF	Bedfordshire and Luton Formulary
FSG	Formulary subgroup
Orx	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 – some outstanding, to be sent via email to Harminder Sehmbi.

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 June 2024 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>Domnisol</td><td>Inclusion of details of specific patient groups on the formulary application for addition to the formulary and ORx.</td><td>B&L formulary updated. Details shared for MK formulary and ORx messaging.</td></tr>
<tr><td>2</td><td>Dexcom One+ sensor</td><td>ICB to communicate with community pharmacy colleagues regarding the switch and CGM standalone guidance to be amended to include this product.</td><td>Message sent on community pharmacy WhatsApp and email groups. The CGM standalone guidance has been updated.</td></tr>
<tr><td>3</td><td>Hydrocortisone 5mg/5mL and 10mg/5ml SF oral solutions and suspensions</td><td>Complete a patient level review for the need to prescribe hydrocortisone liquid and check the formulary at Oxford as the trust likely to be initiating.</td><td>Patients identified and review requested. Oxfordshire formulary only lists plain tablets. Paediatric pharmacist informed.</td></tr>
</table>
</td></tr>
<tr><td>5.</td><td>Items for consideration</td></tr>
<tr><td>5.1</td><td>Heylo leak detection stoma product

Heylo is a new product launched by Coloplast as a leakage notification system, for people with an ileostomy, or colostomy with liquid or mushy outcome. It consists of a sensor layer that sits between the skin and the stoma or ileostomy bag. It is used with a reusable rechargeable transmitter that connects to a smart phone via Bluetooth® to give an audible alarm.

Coloplast’s website states that 92% of people living with a stoma worry about leakage and claim 76% experience leakage at least once a month. It is not necessarily a health need that the NHS has</td></tr>
</table>

No	Agenda Item
	a duty of care to alleviate, although it is not available to purchase, Coloplast are looking to make it a self-care item. Coloplast estimate the 40-50% of patients with an ileostomy could hit the 'required scores' to warrant consideration of the technology based upon their scoring system. Bullens, BLMK's stoma product delivery company have 1,138 patients live on their system in July 2024. 40% would potentially be 455 patients. The list price for one box of 10 sensors is £30.60 (Drug Tariff July 2024). If it assumed bags are changed every 3 days on average, 121 sensors would be required per patient each year, i.e. 12 boxes per annum costs £367.20. The total cost per annum for BLMK would be £167k. It should be noted that the potential number of stoma patients cannot be estimated as this is based upon consistency of stoma output. A stakeholder engagement meeting was held on 31/7/24 and it was felt that it was more important to address the cause of the leaking stoma or ileostomy i.e. review the product being used due to the risk of skin damage rather than managing leaks via an alert. There was also the risk that patients may rely on the leak detection system to change bags and wear the same bag for longer than it would be clinically appropriate. The stakeholders agreed that the product should be non-formulary DNP pending an evaluation and any patients deemed suitable for a trial should obtain the product via Bullens, not via the GP. The proposal is to add the product as Do Not Prescribe pending a full business case/ formulary application following evaluation. CCS district nurses agreed with the proposal. The proposal to designate Heylo leak as a Do Not Prescribe product was agreed by the group.
5.2	**Adult ADHD shared care and transfer of care agreement -ELFT** This SCG has been updated using the BLMK shared care template. Changes include the addition of the Psychiatry UK details, inclusion of guanfacine, information on CAMHS transition and continuing of medication, contact details for adult ADHD services and additional information about dexamfetamine in contraindications/cautions, pregnancy, and breastfeeding. There is advice on the need to inform the DVLA if a patient's condition/medication could affect their ability to drive. This agreement only covers Luton and Bedfordshire patients under the care of East London Foundation Trust. Guanfacine (and dexamfetamine) are not licensed in adults, however the committee noted that guanfacine is in the SCG agreed with Psychiatry UK for adults, so this SCG offers parity (note: Psychiatry UK is the commissioned provider of adult ADHD services in Milton Keynes, and providers care for Bedfordshire and Luton patients under Right to Choose). Guanfacine patient numbers tend to be lower as it is used further down the treatment pathway, as per NICE guidance, and the recent stock shortages may have led to unusual prescribing. JM confirmed that there are 30 patients over 18 on Guanfacine on SystmOne. It was clarified that the transfer of care would require written agreement, not the sharing of care. Shared care is assumed unless primary care specifically declines. Actions: • Specialist to include other medications the patient has tried for ADHD in their correspondence.

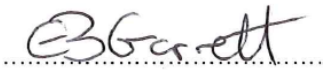
No	Agenda Item
	• The guidance states that CAMHS need to inform adult services when a patient needs to be transitioned into their services. YA requested that this should also include patients under specialists for co-morbid mental health conditions/needs. • IS will be taking the guidance to MedCom for comments. The SCG will be approved following the agreed amendments.
5.3	**Apomorphine Shared Care Guidance** – deferred to November meeting.
5.4	**Melatonin Shared Care Guidance** – deferred to November meeting
5.5	**Aymes ActaGain Protein Shot** This is a new high protein product for oral and tube fed patients. It's phosphate free and low in electrolytes, with all the essential amino acids. High protein products are recommended in patients with pressure and surgical wounds that are not healing to improve skin integrity and prevent breakdown. Supplementation can therefore have the potential for reducing appointments required with district nurses/TVNs. Some patients on enteral feeding may require a lower calorie, higher protein product. However, Aymes ActaGain Protein Shot is not nutritionally complete. The most cost-effective protein product (Protifar) is milk based. ProSource and ActaGain Protein are alternatives which are lactose (and gluten) free. Aymes ActaGain protein shot is comparable to the ProSource range but at a lower price, particularly when comparing products per gram of protein. Most patients should be suitable for ActaGain Protein Shots. However, ProSource products should not be removed as there may be patients (estimated to be less than 5 at any time) who require ProSource due to varying gastric tolerance. Patients could be actively swapped off ProSource products by the hospital dietetic team and it can be provided to patients on discharge. In 2023-24 the spend on ProSource was £74,887. The potential saving per gram of protein if patients were switched to ActaGain Protein Shots could be £32,414. Proposal: ActaGain Protein Shot as a second line, dietitian only recommended product for patients requiring protein supplementation via oral or enteral routes if Protifar is not appropriate. Bedfordshire and Luton dietitians don't use these products as much due to their established Food First project and patients don't like the smell or taste. But KS stated that this product is taken as a medicine rather than an alternative to food. Protifar is suitable for vegetarians, however Aymes ActaGain is beef based and ProSource is pork based. The ProSource plant option is non-formulary and more expensive at £2.10 for 15g of protein and in a larger 45ml sachet. As it is being used as a medicine, people are usually willing to take it even if they would usually avoid these products. KS explained that the use of one recyclable bottle of Aymes instead of several sachets of ProSource could reduce the carbon footprint as the contents expires after 24 hours if kept in the fridge after opening. Aymes ActaGain comes in an outer of 15 x 60ml. It should be requested by the dietitians accordingly to avoid loss to community pharmacies. AH confirmed that it is available from the wholesalers.

No	Agenda Item
	The group accepted the proposal for ActaGain Protein Shot as a second line, dietitian only recommended product for patients requiring protein supplementation via oral or enteral routes if Protifar is not appropriate. Actions: • Dietitians to request Aymes ActaGain Protein Shots in multiples of 15 in their letters to the GP. • ORx messaging to recommend prescribing in multiples of 15.
5.6	**Combination antidiabetic tablets** NICE NG 28 recommends an individualised approach to diabetes care considering personal preferences, comorbidities, and the risks from polypharmacy. Fixed-dose combination oral antidiabetic medicines offer a convenient alternative to simplify administration. Reducing pill burden may support adherence to treatment although there is currently no evidence to support this. Historically, combination tablets were avoided in MK but as the cost difference reduced, they were added to the formulary with the advice that use should be restricted. B&L avoids the addition of combination tablets on the basis that patent expiry is delayed. For example, saxagliptin's patent expired in October 2024, whereas the saxagliptin and metformin combination tablet's patent is set to expire in March 2026. A decision to revisit the formulary status was taken for alignment and as a cross-section of products have dropped in price. The combination tablets can be larger and more difficult to swallow e.g. metformin 500mg m/r (16mm x 8.2mm) vs dapagliflozin 5mg / metformin 1g tablets (21.5mmx 10.5mm). Patients may be confused about which medicine to stop due to sick day rules and two medicines for diabetes would be stopped when only one is required. Increased adverse drug events may be experienced i.e., from the use of standard release metformin instead of modified release. Some doses may be split when used in combination preparations, when the single components could have been prescribed once daily. Medication recognition may be more difficult and there may be a greater risk of picking errors with combination descriptors. Titrating doses is made more difficult when having to account for the two different drugs in the preparation. Despite being designated as non-formulary on B&LF, but some are included in MKF spend was £56,289 between Jan and March 2024. The proposal is to designate combination products as green when cost effective and only if the DPP4i, is sitagliptin. Amber designation when slightly more expensive (note: metformin /sitagliptin – combination now category M, prescribing would be generic and not by brand). Red designation when significantly more expensive. The CCS diabetic team agree with the proposal given that dose adjustment can become more difficult with a combination preparation and compliance may be reduced if the larger tablets are difficult to swallow. But there may be a few patients with a preference and needing to reduce their tablet burden, in which case it would be preferable to allow them as second line options. AG suggested, due to the lack of support for the preparations, that they be designated as non-formulary, and any prescribing would come under the formulary 80:20 rule. QK explained that Bedfordshire Trust does not stock combination preparations and are unlikely to start. Patients are prescribed the individual doses when admitted, aiding the nursing team and for dose adjustment. It was noted that current prescribing was low.

No	Agenda Item
	AH explained that low numbers of prescribing would mean that community pharmacies would probably be ordering in for the specific patients and if there was a stock issue, they would revert to the individual ingredients. The proposal agreed by the group was to designate the combination preparations non-formulary. Any patients requiring a combination product due to compliance issues or to reduce the pill burden would fit into the 20% of patients that don't fit into the formulary.
5.7	**Latanoprost 50mcg/ml preservative free eye drops (multi-dose bottle). Lotacryn®** Lotacryn comes in a 2.5mL bottle £7.99 (1 month), is cheaper than current brand leader Monopost (Cat C drug tariff (Aug24) £8.49 – 30-unit dose vials (UDVs)) and can significantly reduce CO_2. There is a potential annual cost saving of £14,631 and CO_2 saving of 823 kg if using Lotacryn instead of Monoprost. Alignment of the formularies is required as latanoprost 50mcg/ml single-use drops are on MKF (as SpA) but not on the B&LF. Lotacryn is a sterile solution with no preservatives, however the buffering system does contain phosphate-based substances. Patients unsuitable to switch could still access UDVs if clinically appropriate. The solution from the multi-dose bottle can be used for up to 30 days after first opening for administration to the affected eye(s). Contact lenses should be removed before instillation of the eye drops and may be reinserted after 15 minutes. The proposal is to add the Lotacryn multi-dose bottles to the formularies as SpA, first line option when a preservative free formulation is required in preference to UDVs. UDVs to be designated as non-formulary; existing patients may remain on them if not possible/suitable to switch to Lotacryn. NW has had feedback that the hospitals are still recommending UDVs rather than the multidose bottles which have been added to the formulary are so this needs to be fed back. The proposal was agreed by the group. AG has contacted Mr Lobo from Moorfields regarding the recommendation of approved multidose preservative free formulations rather than the UDVs. He is supportive of this and will share with the team.
5.8	**Biosimilar Ustekinumab** Ustekinumab is on the local formularies and in use in line with NICE TA recommendations: • Ustekinumab for the treatment of adults with moderate to severe psoriasis, NICE TA180, issued September 2009. • Ustekinumab for treating active psoriatic arthritis, NICE TA340, issued June 2015. • Ustekinumab for moderately to severely active Crohn's disease after previous treatment, NICE TA456, issued July 2017. • Ustekinumab for treating moderately to severely active ulcerative colitis, NICE TA633, issued June 2020. In addition, local agreements/pathways are in place:

No	Agenda Item
	• BLMK Treatment pathway for Severe Plaque Psoriasis, last updated September 2023 • BLMK Treatment Pathway for Active Psoriatic Arthritis (non-Axial PsA) after inadequate response to DMARDs, last updated December 2023. • BLMK Crohn's Disease -Moderate to Severe Disease Treatment Pathway, last updated September 2023. • BLMK Ulcerative Colitis (Moderate to Severe) – Treatment Pathway AFTER failure of conventional therapy, last updated May 2024. The originator brand, Stelara®, lost its patent exclusivity on 19th July 2024, after which biosimilar versions of ustekinumab have been marketed in the UK. At launch, ustekinumab biosimilars are not licensed for ulcerative colitis. The ongoing patent exclusivity for ulcerative colitis has been challenged in court and the judge ruled the patent to be invalid. The result of any potential appeal process into this indication should be completed by October/November. A national procurement process has been undertaken for the currently available biosimilars and made available for use within the NHS. The framework commenced on 1st September 2024. Stelara® is available as a pre-filled pen but this is not available for any biosimilar brand at launch. However, usage of the pen is low. Choice based on local Trusts' decision and biosimilar implementation plan: • Pyzchiva® (at BHFT and MKUH) and Wezenla® (MKUH) At MKUH, it is anticipated that use of Pyzchiva will be for Gastro (2/3 of ustekinumab usage), whilst Wezenla will be for Dermatology. The split between the products aims to maintain market share across biosimilars. With an estimated 45-50% uptake within the 2024/25 financial year, savings of up to £1.3m would be generated within the ICS. The proposal is to add the Pyzchiva and Wezenla biosimilars to the formularies was approved.
6	**Minor amendments log** 6 Minor amendments log September 2024.c
AOB	Newly licensed generic mexiletine 50mg, 100mg and 200mg capsules have been added to the formulary for the treatment of ventricular arrhythmias as red drugs for specialist prescribing only. Mexiletine was already on formulary for the treatment of non-dystrophic myotonic disorders (NB: Namuscla brand; recommended for use in NICE TA748; NHS England commissioned). Actions: Additional formulary entry required for the different licensed indications – to be actioned by the hospital team. Rivaroxaban has moved to category M in the drug tariff, and this may have an impact on the DOAC position. The following medicines were noted as being de-branded: • Vipidia® name has been removed from alogliptin (patent still in place). It is manufactured by Takeda.

No	Agenda Item
	• Salazopyrin® name has been removed from Sulphasalazine – now generic. It is manufactured by Pfizer. • Ralvo® name has been removed from Lidocaine patches – now generic. It is manufactured by Grunenthal. Meeting dates for 2024 are available on BLMK ICB Website – Formulary Page https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/

Chair Signature: 

Date: 07.01.2025