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

Date: 16th April 2024
Time: 12.30 - 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	✓	
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		✓	
Qiratulain Khan	QK		✓	
Helen McGowan	HM		✓	
Rushnara Begum	RB		✓	

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 February 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>Nutriprem Human Breast Milk Fortifier</td><td>Request for Nutriprem Human Breast Milk Fortifier was considered Feb 2024 – it was felt that GPs were not best placed to continue to supply of a short, fixed course of a specialist product. Dietician oversight also required and concerns raised about interface communication failure leading to prescribing errors in newly discharged premature infants. Further exploration of a safe and effective pathway to be taken forward outside of FSG with updates to the meeting as it progresses.</td><td>Open – pathways being explored</td></tr>
<tr><td>2</td><td>Oxybutynin patches</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: To feedback rationale for use of liquids over patches in elderly patients (NB: patches are not listed on prescribing</td><td>AA to confirm and close</td></tr>
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No	Agenda Item
	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. Update April 2024: Bedford hospital paediatrics team confirmed they use oxybutynin liquid for overactive bladder in paediatrics. Solifenacin is not licensed for this indication therefore it will need to remain on Formulary for these patients.
5.	**Items for consideration**
5.1	**Cytisine 1.5mg tablets for smoking cessation** Cytisine is a new drug to the UK market - the use of Cytisine allows for a gradual reduction of nicotine dependence by relieving withdrawal symptoms. Cytisine competes with nicotine for the same receptors and gradually displaces nicotine due to its stronger binding. NICE have carried out an "exceptional review" of cytisine and are planning to update NG209 (Tobacco: preventing uptake, promoting quitting and treating dependence) as a result of this review – Surveillance decision | Evidence | Tobacco: preventing uptake, promoting quitting and treating dependence | Guidance | NICE. NICE concluded that the available evidence confirms that cytisine has a comparable effect, safety and cost to currently recommended products (varenicline, nicotine-containing e-cigarettes and nicotine replacement therapies (NRT)). No time frame for the update is currently visible on the NICE website. Public Health Services: Stop smoking services – two across BLMK 1. Turning Point, who cover Luton and are part of the Total Wellbeing Luton. 2. Stop smoking service who cover Bedfordshire and Milton Keynes. Intention to align wording/content and personalise documents with logos / links after. Proposal: • To add as green to both joint formularies, as a second line treatment option after NRT. • Smoking cessation teams will assess patients for suitability, fill in the agreed proforma, then write to the GP with a request to prescribe. • Primary care prescribers may also initiate if confident to do so and running a smoking cessation service.

No	Agenda Item
	• Prescriptions will be re-charged to PHE services in line with other similar therapies. It is not intended that cytisine will be used to help patients quit vaping. The group discussed the main side effect of hypertension and agreed that blood pressure should be measured at baseline and patients can be advised to self-monitor during treatment. It was noted that treatment is a single 25-day course, and that off-label use is not recommended. The proposal to add cystisine to the formularies as green was approved. Optimise messaging to be used to support appropriate use (acute 25-day course, with reducing dosing regimen). **Post meeting note**: The product has recently been added to the BNF as cytisinicline and, more recently (post-FSG), has been added to SystmOne. Action– to update paperwork and finalise with new name. Also add dosing schedule to SystmOne central Formulary.
5.2	**Tadalafil once daily preparations (2.5mg and 5mg) for erectile dysfunction** Tadalafil is licensed for the treatment of Erectile Dysfunction (ED.) Currently 10mg and 20mg are green on both formularies for this indication, with the stipulation that they are prescribed on the NHS only where a patient meets the NHS SLS criteria. The 2.5mg and 5mg strengths are licensed for once daily, rather than prn, use and are currently non-formulary as they were previously listed as a low value medicine by NHS England. In August 2023, NHSE updated their recommendations on low value medicines and removed tadalafil 2.5mg and 5mg from these recommendations. The group noted that the 2.5mg tablets are considerably higher cost than any other tadalafil preparation, and that this strength is only recommended for use for patients who cannot tolerate the 5mg dose (5mg once daily is the starting dose for who anticipate sexual activity at least twice a week). NB: 5mg is not suitable for cutting in half, as the tablets are film-coated. The group discussed concerns raised regarding use of 2.5mg first then up titrating – clarity needed on Formulary/Optimise for this. JWa also raised that patients often ask for tadalafil where sildenafil is not working. The addition of tadalafil 2.5mg and 5mg tablets to the formularies was approved as follows: • Green traffic light, second line to sildenafil, and only in line with the licensed indication. Tadalafil 2.5mg tablets are restricted for use only when the 5mg dose is not tolerated. • Clear Optimise messaging to be developed, and wording included in the formularies, regarding the appropriate dosing recommendations i.e. start with 5mg and reduce to 2.5mg if appropriate (higher strength not tolerated).

No	Agenda Item
5.3	**Melatonin for REM sleep disorder in Parkinson's disease** A proposal was presented to add melatonin for the management of REM sleep disorder in Parkinson's Disease, to the Beds & Luton Formulary to align with the MK Formulary and in line with recommendations in NICE NG71. NICE NG71 recommends melatonin as a 'consider' option, alongside clonazepam to treat rapid eye movement (REM) sleep behaviour disorder "if a medicines review has addressed possible pharmacological causes". Melatonin was noted to be better tolerated than clonazepam. Treatment is long term with regular reviews in either community Parkinson's Disease Nurse clinics or annually at consultant reviews within secondary care. If treatment is ineffective plans will be made to stop treatment and consider alternative therapies. Specialists within Beds/Luton are currently prescribing melatonin for this indication (in approximately 30-50 patients and support addition to the formulary in approximately 30-50 patients. The proposal to add melatonin to the Beds/Luton Formulary, with SpIS traffic light designation, was approved. 28 days supply to be issued from the Trust initially, as per contracting arrangements.
5.4	**Safinamide for Parkinson's disease** Deferred to the next meeting as previously considered by the Bedfordshire and Luton Joint Prescribing Committee in 2019 and carried a negative recommendation – full review required.
5.5	**Bimi (Bimatoprost 300mcg/mL) preservative free eye drops** Request for addition of Bimatoprost 300mcg/mL Preservative free multi-dose eye drop bottles as alternative to single-use eye drops (Unit Dose Vials, UDVs). Currently MK Formulary has 300mcg/mL single-use eye drops as SpA, but the Beds/Luton Formulary only has 100mcg eye drops. The 300mcg/mL strength was proposed to be added to align with MK and support current use (SpA). Potential for >£10k annualised cost savings to BLMK for using multi-dose bottles rather than UDVs. Additional points/considerations: • Supports the NHS green agenda with significant reduction in CO2 emissions (reduced plastic / packaging) • Consider keeping UDVs for patients unable to switch / use multi-dose bottles. • Engagement with hospital specialists is required to ensure that UDVs are not initiated in the future. • Bimi brand is a sterile solution with no preservative. The solution from the multi-dose container can be used for up to 90 days after opening. The predominant name on the formulary will need to be generic (due to frequent changes in the most cost-effective branded generics). Optimise to be used to drive the brand choice in primary care. Trusts to promote green agenda as a reason for using BIMI to patients – noting bimatoprost is started in secondary care with a focus on green agenda.

No	Agenda Item
	The proposal was approved.
5.6	**Dimaz (Dorzolamide 2%) eye drops** Request for addition of Dorzolamide 2% Preservative free multi-dose eye drop bottles as alternative to single-use eye drops. Currently the MK Formulary has 2% single-use eye drops as SpA, but the Beds/Luton Formulary does not specify preservative free (single or multi-dose eye drops) – these were therefore proposed to be added to the Beds/Luton formulary (SpA) to align with MK and support current use. Potential cost savings of >£50k. Additional points/considerations: • Supports the NHS green agenda with significant reduction in CO2 emissions (reduced plastic / packaging). • Consider keeping UDVs for patients unable to switch / use Multidose bottles. • Dimaz (Scope) is a sterile solution with no preservatives. The solution from the multi-dose bottle can be used for up to 28 days after first opening for administration to the affected eye(s). • Bausch + Lomb – Vizidor (Dorzolamide 2% in a preservative free, multi-dose bottle maybe a more cost-effective option – being investigated for savings opportunities across BLMK). The proposal was approved. The predominant name on the formulary will need to be generic (due to frequent changes in the most cost-effective branded generics). Optimise to be used to drive the brand choice in primary care with a focus on green agenda.
5.7	**Codimaz (Dorzolamide 20mg/ml & Timolol 5mg/ml (2%/0.5%)) eye drops** Request for addition of Dorzolamide 20mg/ml & Timolol 5mg/ml (2%/0.5%) Preservative free multi-dose eye drop bottles as alternative to single-use eye drops. Currently MK Formulary has Cosopt (Dorzolamide/Timolol) eye drops to “aid compliance for those patients requiring both a carbonic anhydrase inhibitor and beta-blocker” (SpA) but do not have preservative free eye drops. The Beds/Luton Formulary lists the combination but currently does not specify preservative free (single or multi-dose eye drops) (SpA) – proposal that the preservative free multi-dose eye drop is added in line with significant current use. Potential for >£40k cost savings. Additional points/considerations: • Supports the NHS green agenda with significant reduction in CO2 emissions (reduced plastic / packaging). • Consider keeping UDVs for patients unable to switch / use multi-dose bottles. Codimaz (Scope) is a sterile solution with no preservatives. The solution from the multi-dose bottle can be used for up to 28 days after first opening for administration to the affected eye(s). Bausch + Lomb – Vizidor Duo (Dorzolamide 2% / Timolol 0.5% in a preservative free, multi-dose bottle) maybe a more cost-effective option – being investigated for savings opportunities across BLMK.

No	Agenda Item
	The proposal was approved. The predominant name on the formulary will need to be generic (due to frequent changes in the most cost-effective branded generics). Optimise to be used to drive the brand choice in primary care with a focus on green agenda.
5.8	**Ivermectin cream (Soolantra) for inflammatory papules and pustules of rosacea** Ivermectin 10mg/g cream is recommended as first line treatment for the management of mild to moderate papules and pustules associated with Rosacea by the Primary Care Dermatology Society (PCDS) and within the NICE CKS. Ivermectin cream is currently non-formulary in Beds and Luton, however there is significant prescribing noted from ePACT, and SpA on the MK formulary. However, given the NICE and PCDS recommendations it was proposed that this is appropriate to be started in primary care where a diagnosis of rosacea is clear. Inclusion on both formularies as green will improve access to treatment without the need for secondary care referral. Ivermectin cream is effective and well tolerated in clinical trials and is a non-antibiotic option for the management of mild to moderate rosacea – reducing the impact on antimicrobial resistance. It is also less irritant than other preparations. The proposal was approved – for inclusion of ivermectin 10mg/g cream as green first line on the formularies. Cosmetic treatments for rosacea (i.e. erythema only) will remain non-formulary.
5.9	**Azelaic acid 15% for inflammatory papules and pustules of rosacea** Azelaic acid 15% gel is recommended as an alternative topical first line treatment for the management of mild to moderate papules and pustules associated with Rosacea by the Primary Care Dermatology Society and within the NICE CKS. Azelaic acid 15% gel is currently non-formulary in Beds and Luton however there is significant prescribing noted from ePACT. It was therefore proposed that azelaic acid gel is added to the Beds/Luton formulary as green. The product is already on the MK formulary as green. Azelaic acid 15% gel is a non-antibiotic option for the management of mild to moderate rosacea – reducing the impact on antimicrobial resistance (currently the only topical option on Beds and Luton formulary is metronidazole gel). The proposal was approved – to add azelaic acid 15% gel to the Beds/Luton formulary as green second line, to align with MK and national guidance recommendations. Action – Strengthen non-formulary wording on Optimise for Mirvaso (brimonidine gel).
5.10	**Alternative guide to prescribing specials** The subgroup was presented with a new support tool which has been created to assist practices when prescribing specials – this includes recommendations for alternatives based on cost, licensing, and local formularies. The guidance also supports the cost saving element of the Prescribing Incentive Scheme (PIS) for 2024/25. Practices will be

No	Agenda Item
	able to identify which 'specials' are being prescribed and utilise this guide to review and consider alternatives where clinically deemed appropriate for the patient group. Appropriate messages have been added to ORx to reduce prescribing of specials. The guidance will continue to be reviewed and updated on a regular basis to ensure it is up to date. AH – raising awareness that the guidance exists would be useful but expressed concerns about colleagues using out of date versions. To be added to password protected part of the website. Concerns raised about copyright, hence the proposal it is added to the password protected section. The password is normally 'remembered' by the computer/laptop so won't need to be remembered to enter each time. The password is expected be available to anyone from within the BLMK system, on request. This section of the website is still undergoing development. The group agreed that the document is a useful support tool and approved it with minor amendments discussed at the meeting. The chair thanked AGa for her time and effort producing the guidance.
5.11	**Freestyle Libre 2 Plus and standalone CGM guidance update** 1. Addition of Freestyle Libre 2 Plus (FSL2 Plus) to the Formularies. The upgraded sensor is more accurate, carries an additional day of life in the sensor (15 vs 14 days) and is compatible with the same apps e.g. Libreview as FSL2. The rebate price is also applicable and is therefore the same cost as FSL2 sensors. The intention is to bulk switch patients from FSL2 to FSL2 Plus with notification via letter. 2. The standalone CGM guidance has been updated to reflect the decision at the previous meeting regarding FSL3, and the above proposal regarding FSL2 Plus. The document has also been simplified and summarised on to one page. The subgroup noted that, while FSL2 Plus was added into the Drug Tariff on 1st April, and is available on SystmOne, it is not yet compliant with electronic prescribing (it is listed on S1, but not yet active via EPS). FSL2 Plus is live and available to order via the manufacturer, Abbott's, ordering portal. Monthly order limits for community pharmacies are expected to be extrapolated from existing order limits for FSL2. The Freestyle Libre app, Librelink which is used by most patients on their smart phone, and the specific FSL reader, both contain a countdown for the number of days left; for FSL2 this starts at 14 days and for FSL2 plus this starts at 15 days. Once only a few days are left it turns red and counts down in days and then hours to the time of the sensor change. The patient information leaflet for FSL2 plus states the sensor lasts for 15 days. Community pharmacists and diabetes teams may also be able to support patient education around the frequency the sensors need to be changed (15 days for FLS2 Plus vs 14 days for FLS2).

No	Agenda Item
	The proposal to add FSL2 Plus to the formularies, and to bulk switch patients from FSL2, was approved. The updated standalone CGM guidance was approved.
5.12	**Aflibercept 8mg injection** Local Ophthalmology specialists requested addition of a new product to the formularies: aflibercept (Eylea) 114.3 mg/ml solution for injection (8mg dose). Aflibercept 2mg injection is already on both formularies, and NICE approved for a range of indications. Aflibercept 8mg is licensed for the treatment of AMD and DMO. NICE do not intend to consider aflibercept 8mg separately, as it is too similar (in terms of product and price) to the existing 2mg product. NICE has already issued positive recommendations for AMD and DMO for aflibercept 2mg. The product offers benefits in terms of increased interval between injections resulting in fewer patient visits and increased clinic capacity, and the manufacturer has confirmed that the cost will be the same for both aflibercept (Eylea) products. The 8mg product is proposed to be an additional treatment option alongside aflibercept 2mg, ranibizumab, brolucizumab and faricimab. Ranibizumab and brolucizumab are rarely used. Faricimab is also used in the Trust as it also has the benefit of extended dosing interval and clinicians are reporting a good response to the drug. Discussion with local clinicians has indicated that new patients starting on aflibercept are likely to be started on the 8mg, rather than the 2mg dose, and existing patients on 2mg may be switched to 8mg depending on response. The expected loss of patent exclusivity, and availability of biosimilar aflibercept in 2025, was discussed. There are indications that a biosimilar of the 8mg product, in addition to the 2mg, *may* be available following the patent expiry next year. Further information is awaited to confirm this. Aflibercept (Eylea) 8mg injection was approved for addition to the formularies as a red (specialist only) medicine. To be added to the intravitreal injections pathway, in the same place as aflibercept 2mg, for the licensed indications of AMD and DMO (see agenda item 5.2).
5.13	**Tocilizumab biosimilar (for noting)** Proposal to add the newly available tocilizumab biosimilar (Tyenne) to both formularies. This will be used in the same place as existing treatment pathways as the originator product (RoActemra). The biosimilar is available in the following formulations: SC 162mg/0.9mL, IV 200mg in 10mL, IV 400mg in 20mL and 80mg in 4mL. Patients will be informed and consented to the switch by specialist teams. The group noted the addition of the tocilizumab biosimilar products to the formularies (red – specialist only).
5.14	**Slynd** Deferred to APC to be discussed alongside contraceptive guidance.

No	Agenda Item
6	Minor amendments log 6 Minor amendments log for April 2024 8.4.
AOBs	**Metoject pens** The Metoject (methotrexate) pen device has recently been changed by the manufacturer and a link to the information has been added to the formulary. The new pen is simple to use, but patients should be made aware of, and counselled on, the change. **Tirzepatide for GLP1 shortage** Tirzepatide has a dual mode of action, which produces improved HbA1C and weight outcomes in comparison with GLP1 receptor agonists. Tirzepatide is NICE approved for the management of T2DM. Oral semaglutide is recommended as first line alternative during the period of supply shortages with the injectable GLP1 agonist agents, but tirzepatide may also be considered. Only 2 strengths of tirzepatide are currently available – 2.5mg and 5mg. The recommendation for the use of tirzepatide currently only applies to T2DM. Tirzepatide is also licensed for the management of obesity and there is a NICE TA in development for this indication. Its use for obesity is currently non-formulary and is not recommended in advance of the publication of guidance from NICE. **Gonadotrophin Releasing Hormone Analogues (GnRHa) for paediatric use** In March 2024, NHSE published a clinical policy on the use of puberty blockers in children and young people (CYP) with gender dysphoria. Use of Puberty suppressing hormones (PSH) are not available as a routine commissioning treatment option in this context and is not recommended. This policy recommendation prompted a review of local prescribing of GnRHa in children and a review of the formulary entries. Review of ePACT/local prescribing data identified a small amount of prescribing of GnRHa in CYP, some of which was for gender dysphoria, and some for other indications e.g. precocious puberty. Practices prescribing for gender dysphoria have been contacted, informed of the NHS England policy recommendations, and advised to stop prescribing. Formulary entries have been reviewed and the link to the NHSE guidance has been added. A new entry has been added for other indications for the use of GnRHa in paediatrics to confirm this is Red, specialist only. Meeting dates for 2024 are available on BLMK ICB Website – Formulary Page https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/

Chair signature: