

BEDFORDSHIRE, LUTON AND MILTON KEYNES AREA PRESCRIBING COMMITTEE

Meeting Notes

Date: 28 February 2024

Time: 12.30- 2.15pm

Venue: Microsoft Teams

Attendees:

Name	Initial	Role
Dr Muhammad Nisar	MN	Chair (Medical Representative, Bedfordshire Hospitals NHS Trust)
Mojisola Adebajo	MA	Place Based Lead Pharmacist – Luton
Reginald Akaruese (until 2pm)	RA	CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes)
Dr Marian Chan	MC	Medical Representative, Bedfordshire Hospitals NHS Trust
Janet Corbett	JC	Milton Keynes Hospital Pharmacy Representative (Pharmacy Programme Manager, Milton Keynes Hospital)
Naomi Currie	NC	Place Based Lead Pharmacist - Bedford
Matt Davies (deputy for Fiona Garnett until 12.46pm)	MD	Place Based Lead Pharmacist – Central Bedfordshire
Dupe Fagbenro (until 2pm)	DF	ELFT Pharmacy Representative (Deputy Chief Pharmacist (Luton and Bedfordshire), ELFT)
Fiona Garnett (from 12:46pm)	FG	Associate Director and Head of Medicines Optimisation BLMK ICB
Anne Graeff	AG	Commissioning Lead Pharmacist, BLMK ICB (Professional Secretary)
Cheryl Green	CG	Patient Representative
Carole Jellicoe (from 12:42pm)	CJ	Nurse Representative (Independent Prescriber)
Dr Lindsay MacKenzie	LM	Deputy Chair / Place Based Lead GP Bedford (deputy to Dr Wilson)
Dr Kate Randall (from 12:37pm)	KR	Place Based Lead GP – Central Bedfordshire

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

Dr Mitan Sarkar	MS	Place Based Lead GP - Luton
Dr Jenny Wilson	JW	Place Based Lead GP - Bedford
Dona Wingfield	DW	Chair of Medicines Safety Group / Bedfordshire Hospitals Trust Pharmacy Representative (Medicines Use and Quality Manager, Bedfordshire Hospitals Trust)

In attendance:		
Saema Arain	SA	ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton)
Taiya Large	TL	Formulary and Medicines Safety Pharmacist BLMK ICB
Dr Joy Mutitika	JM	Medical Representative, Keech Hospice
Nikki Woodall	NW	Lead Medicines Optimisation Technician, BLMK ICB
Clare Morlidge (in attendance for agenda item 5.3)	CM	Consultant Renal Pharmacist, East and North Hertfordshire NHS Trust
Helen McGowan (in attendance for agenda item 5.7)	HMcG	Place based Pharmacist, BLMK ICB
Samina Hassanali (observer)	SM	Place based Pharmacist, BLMK ICB
Harminder Sehmbi (observer)	HS	Pharmacy Team Coordinator, BLMK ICB

Apologies:		
Nicola Ainsworth	NA	Consultant in Public Health
Rafal Ali	RA	Commissioning Pharmacist, BLMK ICB
Sally Cartwright	SC	Consultant in Public Health
Helen Chadwick	HC	Milton Keynes Hospital Pharmacy Representative (Chief Pharmacist, Milton Keynes Hospital)
Candy Chow	CC	Chair of Wound Care Group
Alice Green-Smith	AGS	Representative, St John's Hospice
Sandra McGroarty	SMcG	Commissioning Pharmacist, BLMK ICB
Dr Dush Mital	DM	Medical Representative, Milton Keynes Hospital
Kike Pinheiro	KP	Representative, Willen Hospice
Andrew Tse	AT	Milton Keynes Hospital Pharmacy Representative (Medication Safety Officer, Milton Keynes Hospital)
Dr Jonathon Walter	JWa	Place Based Lead GP – Milton Keynes
Dr Sarah Whiteman	SW	Chief Medical Director, BLMK ICB
Sharon Wilmore	SWi	PA to MOT, BLMK ICB (admin support)



No	Agenda Item	Action
1.	<p>Welcome, Introductions and Apologies</p> <p>The Chair welcomed everyone to the meeting. Apologies were received and noted as above. The meeting was confirmed as quorate.</p> <p>The Chair welcomed Clare Morlidge (in attendance for agenda item 5.3), Helen McGowan (in attendance for agenda item 5.7), Samina Hassanali (observer) & Harminder Sehmbi (observer) to the meeting.</p> <p>The Chair thanked Reena Pankhania for her service to the APC, the Formulary Subgroup and the legacy Bedfordshire and Luton Joint Prescribing Committee, and Sharon Wilmore for her service to the APC, and wished them all the best for the future.</p>	
2.	<p>Declarations of Interest</p> <p>The Chair invited the members to reconfirm their current declarations on the Register of Interests and advise of any new declarations.</p> <p>All members confirmed their declarations were accurate and up-to-date.</p> <p>The Chair invited members to declare any declarations relating to matters on the Agenda.</p> <p>All other members confirmed they have no declarations in relation to matters on the Agenda.</p>	
3.	<p>Minutes of 06 December 2023 APC meeting</p> <p>The minutes of the meeting held on 06 December 2023 were approved.</p>	
4.	<p>Matters Arising</p>	
4.1	<p>Feedback on miscellaneous actions not included on the agenda from APC meetings</p>	
4.1.1	<p>Shared care patient information leaflet</p> <p>Leaflet to be introduced into practice with BHFT Rheumatology and feedback sought from patients to 'test' the patient acceptability and accessibility of the leaflet.</p> <p>Update 28/02/24 – trials of the leaflet have not yet begun, but initial feedback from the Rheumatology nurses is that it will be time-consuming and not felt to be adding to the process of informing patients and obtaining consent for shared care. Meeting planned next week between BHFT Rheumatology team and ICB Medicines Optimisation team. For further discussion. This is an ongoing action.</p>	MC



No	Agenda Item	Action
4.1.2	<p>Antimicrobial guidelines</p> <p>To be confirmed whether Otigo ear drops (for otitis media) may be used in patients with a perforated tympanic membrane.</p> <p>Update 19/12/23 – Otigo is not suitable for use in the presence of a perforated tympanic membrane (confirmed from product SPC). It was proposed and agreed that the action could be closed.</p>	Close action
4.1.3	<p>Antimicrobial guidelines</p> <p>Otitis externa section to be updated to include ciprofloxacin drops as an alternative treatment option.</p> <p>Update 06/02/24 - the guideline has been updated and uploaded onto the Medicines website. It was proposed and agreed that the action could be closed.</p> <p>A query was raised about whether the MHRA Drug Safety Alerts on fluoroquinolones would apply when the agents are used topically. The safety alert (see agenda item 7.0) relates to oral use of fluoroquinolones. Topical use would not be expected to result in the same systemic effects as oral treatment. To be reviewed and be confirmed.</p>	Close action NC
4.1.4	<p>Osteoporosis guidelines</p> <p>Working group to be formed to review the guidelines to include further information on when to refer to secondary care, counselling and links to patient information, and to consider the guidance needed for strontium (SCG, prescribing guidance, or alternative option)</p> <p>Update 06/02/24 - this has been delayed due to other priorities. This is an ongoing action.</p>	SMcG
4.1.5	<p>Linezolid prescribing guidance</p> <p>Beds/Luton formulary entry wording regarding FP10 prescribing for linezolid to be reviewed to resolve confusion in relation to the wording. MKF formulary status to be changed to SpA.</p> <p>Update 06/02/24 - both formularies have been updated. It was proposed and agreed that the action could be closed.</p>	Close action
4.1.6	<p>Rimegepant for treating migraine (NICE TA919)</p> <p>To be added to both formularies with Green traffic light status and additional wording to highlight the appropriate place in therapy.</p> <p>Update 06/02/24 - both formularies have been updated. It was proposed and agreed that the action could be closed.</p>	Close action
4.1.7	<p>Daridorexant for treating long-term insomnia (TA922) - information on CBTi providers to be shared post-meeting with committee members and wider via the Primary Care Bulletin (PCB).</p> <p>Update 03/01/24 - information shared with committee members 11/12/13 and in the PCB on 09/01/24. It was proposed and agreed that the action could be closed.</p>	Close action
4.1.8	<p>Daridorexant for treating long-term insomnia (TA922)</p> <p>The outcome of the ELFT NICE implementation group discussion re daridorexant to be shared to ensure there is a joined up approach.</p> <p>Update 16/12/23 - the ELFT NICE implementation group have discussed and noted the NICE TA. The group noted that most prescribing will take place in primary care but discussed application within mental health. People with mental health conditions will likely follow the treatment pathway for their condition first before daridorexant would be considered as a treatment option for long-</p>	Close action



No	Agenda Item	Action
	term insomnia. Information shared within ELFT that CBTi is available across BLMK, and the appropriate use of daridorexant in line with the NICE TA. It was proposed and agreed that the action could be closed.	
4.1.9	Daridorexant for treating long-term insomnia (TA922) Optimise Rx messaging to be put in place to support appropriate prescribing, in line with NICE recommendations. Update 07/02/24 - on the Optimise workplan, to be updated after February APC (once the daridorexant prescribing support information has been reviewed/approved – see agenda item 5.1). It was proposed and agreed that the action could be closed.	Close action
4.1.10	Daridorexant for treating long-term insomnia (TA922) Daridorexant to be added to both formularies with Green restricted TLS and additional information regarding the NICE TA requirements on CBTi. Update 06/02/24 - both formularies have been updated. It was proposed and agreed that the action could be closed.	Close action
4.1.11	Tirzepatide for treating type 2 diabetes (TA924) Tirzepatide to be added to both formularies with Green TLS. Update 07/02/24 - both formularies have been updated. It was proposed and agreed that the action could be closed.	Close action
4.1.12	Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction (HFpEF) Formulary entries to be updated to reflect agreed Green TLS for HFpEF and link to the prescribing support information to be added. Update 07/02/24 - both formularies have been updated. It was proposed and agreed that the action could be closed.	Close action
4.1.13	SystemOne local formulary Wording in the S1 formulary for oral contraceptives and HRT to be reviewed to ensure it is in line with current practice and fit for purpose. Update 06/02/24 - wording has been reviewed and agreed to leave unchanged at present. To be reviewed as appropriate in the future in line with any agreed local guidance on contraceptives. It was proposed and agreed that the action could be closed.	Close action
4.1.14	Pharmacy First Concerns regarding lack of visibility to community pharmacists of prescribing outside of GP practices (e.g. secondary care, dentist) to be fed back to the national team. Update 20/02/24 - the concerns have been fed back to the regional and national teams and Community Pharmacy Integration Lead will continue to monitor it. It was proposed and agreed that the action could be closed.	Close action
4.1.15	Pharmacy First Concerns regarding knowledge base of participants with regards to the contraception service to be discussed as part of the work programme to develop local contraception guidance. Update 06/02/24 - discussions are ongoing. This is an ongoing action.	JW/ SMcG



No	Agenda Item	Action
5.	Items for consideration at meeting	
5.1	<p>Daridorexant for long-term insomnia – information for clinicians Prescribing support information has been produced to support primary care clinicians with the implementation of NICE TA922: Daridorexant for treating long-term insomnia. It was agreed at the December APC meeting that GREEN formulary status was suitable for daridorexant, as most prescribing was likely to take place in primary care. Both joint Formularies have been updated to include the information in the NICE TA on the appropriate place in therapy (2nd line after failure of Cognitive Behavioural Therapy for insomnia (CBTi) or when CBTi is not available or is inappropriate.</p> <p>The Committee considered the document and noted:</p> <ul style="list-style-type: none"> • CBTi is the recommended first-line treatment option for long-term insomnia. • Daridorexant is a dual orexin receptor antagonist, acting on both orexin 1 and orexin 2 receptors and equipotent on both. It decreases the wake drive, allowing sleep to occur, without altering the proportion of sleep stages. • The prescribing support document includes information on: <ul style="list-style-type: none"> ○ Therapeutic indications and NICE approved criteria for use. ○ Local providers of Cognitive Behavioural Therapy for insomnia (CBTi). ○ Dosage, including special patient populations (e.g. renal/hepatic impairment, pregnancy/breast feeding). ○ Contraindications and cautions. ○ Drug interactions. ○ Counselling points and sleep hygiene resources. <p>Information on local Talking Therapies providers who offer CBTi was shared with the Committee (also shared at December APC). Digital CBTi is being commissioned nationally by NHS England, but full details are not yet available. This information will be added to the document when confirmed.</p> <p>The Committee discussed the appropriate course of action to be taken if a patient refuses to undertake CBTi or does not engage fully with the CBTi. It was agreed that it may still be appropriate to prescribe daridorexant, but in the context of a full discussion with the patient about the relative benefits of the two treatment options. CBTi has long-term benefits in improving sleep whereas medication will only have benefit when it is being taken. Trial data is available for up to 12 months for daridorexant. Like all hypnotics, daridorexant should be taken for as short a period as possible. Patients should be assessed for response within 3 months and regularly thereafter to check whether it is still working.</p> <p>Decision: The Committee approved the prescribing support information for daridorexant.</p>	AG



No	Agenda Item	Action
	<p>EQIA Assessment: No impact. Prescribing support guidance to assist with the implementation of NICE TA922 only – no deviation from national guidance, as per TA922.</p> <p>BLMK ICB E and D Lead comment: There will be no deviation from national guidance so no further comment relating to EIHR.</p>	
5.2	<p>Contraception guidance Item deferred.</p>	
5.3	<p>SGLT2 inhibitors for treating chronic kidney disease primary care prescribing guidance In September 2022, the APC approved an information document to support primary care clinicians prescribing dapagliflozin for chronic kidney disease (CKD). Subsequently, NICE has published TA942 (Empagliflozin for treating chronic kidney disease) and therefore the guidance has been reviewed and expanded to include the new recommendations for empagliflozin.</p> <p>Following consultation with specialist teams, formulary status of Green is being proposed for both dapagliflozin (SpA status previously agreed) and empagliflozin, except in specific circumstances. SpA formulary status recommended for the following patient groups (Nephrology specialists to advise e.g., via Advice and Guidance prior to initiation in Primary Care for the following categories (as there is no data from large randomised controlled trials for these cohorts)):</p> <ul style="list-style-type: none"> • Kidney transplant recipients. • Polycystic kidney disease. • Lupus nephritis. • ANCA associated vasculitis. • Kidney disease where patient takes drugs which suppress the immune system. <p>The Committee notes the following additional points:</p> <ul style="list-style-type: none"> • Empagliflozin has broader eGFR eligibility compared to dapagliflozin and therefore more people will likely receive it for chronic kidney disease (CKD) without T2DM. • SGLT2 inhibitors are only recommended for use in patients as an add-on to optimised standard care including the highest tolerated licensed dose of angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers, unless these are contraindicated. • SGLT2 inhibitors are expected to have a class effect and therefore specialists indicate they are likely to use one or the other. • A Green traffic light will be better for patients and allow quicker access to treatment, with the associated morbidity and mortality benefits. Most of the patients will not be eligible for referral to tertiary services. 	



No	Agenda Item	Action
	<p>Decision: The Committee approved the prescribing support information for SGLT2 inhibitors for the treatment of CKD.</p> <p>EQIA Assessment: Positive impact. CKD disproportionately affects patients from lower socio-economic groups and those from Black, Asian and minority ethnic populations. The prescribing guidance will support people with CKD who do not meet referral criteria to renal specialists, to access dapagliflozin or empagliflozin (or canagliflozin where applicable) for this indication. These medicines can be initiated safely in primary care by clinicians and will be supported by Advice and Guidance from the renal specialist teams. (NB: updated following receipt of E&D comments).</p> <p>BLMK ICB E and D Lead comment: Section 3 – Already states that those from a BME background are particularly affected by CKD, and that prescribing guidelines will improve access to SGLT2 inhibitors. This is a positive impact that should be included as such in section 4. ‘Yes’ to the question around impact (it doesn’t have to be negative). <i>Author’s response:</i> section reviewed and updated in response to these comments.</p>	
5.4	<p>Rimegepant for acute migraine – information for clinicians</p> <p>The Committee considered a prescribing information document to support the prescribing of Rimegepant in Primary care. This is specific to the use of Rimegepant for the treatment of acute migraine in line with NICE TA919. The document aims to clarify the role of Rimegepant, aid decision making, and ensure prescribing is in line with NICE recommendations.</p> <p>The Committee discussed and noted the following points:</p> <ul style="list-style-type: none"> • Rimegepant for the treatment of acute migraine is indicated for use in patients who have not responded to at least 2 triptans, or for patients with contraindications to triptans. • Additional information has been added to the document to clarify that Rimegepant should be taken at the onset of headache, not aura. • Initial quantities to be supplied: it was proposed that initial supply should be limited to 4 tablets, to be supplied via acute prescription only, and that there should be no repeat prescribing until efficacy and individual patient need is established. This was agreed by the Committee to be a sensible approach. • Headache diary - clinicians at the meeting advised that patients are advised to keep a headache diary, but they do not generally advise use of a specific template. • If recommending a specific headache diary template, prescribers should take into account patient factors e.g. languages spoken, easy read requirements. <p>A query arose regarding whether there are any concerns with the use of Rimegepant in patients with glaucoma – this is to be confirmed.</p> <p>Post meeting note: no ophthalmological adverse effects, cautions or contraindications are listed in the product information for Rimegepant</p>	AG



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	<p>therefore no specific concerns have been identified for prescribing for patients with glaucoma.</p> <p>Decision: The Committee approved the prescribing support information for Rimegepant for acute migraine.</p> <p>EQIA Assessment: No impact. The guidance supports implementation of the NICE guidance (TA919). Prescribers should discuss the most appropriate headache diary to be used with the patient, taking into consideration the AIS, languages spoken and/or easy read. (NB: updated following receipt of E&D comments).</p> <p>BLMK ICB E and D Lead comment: This is a discussion paper – Suggest discussing the most appropriate headache diary in-line with the AIS and any languages deemed appropriate and/or easy read so that it is noted that equality has been a consideration. <i>Author’s response:</i> section reviewed and updated in response to these comments.</p>	
5.5	<p>Safer Valproate Prescribing</p> <p>The Committee was presented with a briefing paper to update on the progress across the system in implementing the requirements of the Valproate prescribing NPSA alert (November 2023).</p> <p>Actions to date:</p> <ol style="list-style-type: none"> 1. Valproate prescribing group established – subgroup of Medication Safety Group, reporting into APC and upward report to BLMK ICS Quality and Performance Committee for assurance (planned agenda item 7th June 24). 2. Providers’ review of internal guidelines and procedures ongoing. 3. Primary care data review – included in 24/25 primary care Prescribing Incentive Scheme (nomination of valproate champion in each practice). 4. Primary care messaging in SystmONE and Optimise Rx enabled. 5. Agreement that MKPAG position statement regarding completion of PPP forms for defined patient cohorts by GPs should be retracted. All patients to be repatriated to appropriate specialist teams. 6. Development of action and implementation plan. <p>The following points were discussed:</p> <ul style="list-style-type: none"> • Formulary status of valproate: the Committee agreed that, at the current time and while the release of the updated national shared care guideline is awaited, it would be appropriate to retain the current formulary traffic light status of SpA. • No timeframe is currently available for the publication of the updated national valproate shared care guideline. • Clinical and GP representatives on the valproate prescribing group: it was agreed that wider representation is required on the valproate group, to include neurology specialists, mental 	



No	Agenda Item	Action
	<p>health specialists and GPs. Expressions of interest were invited from the Committee and its wider contacts.</p> <ul style="list-style-type: none"> • Chair of the valproate prescribing group – expressions of interest invited from e.g. specialists, quality team. • Capacity concerns within the Trusts were expressed due to increased workload and lack of additional funding. Waiting lists for appointments in the relevant specialities are already extensive. • Trusts are in the process of reviewing and updating internal guidelines which include valproate, with a view to reducing prescribing. • A joined-up process needs to be in place to ensure seamless care across the interface between secondary and primary care. The updating and development of processes for valproate needs to be done with this in mind. <p>Valproate prescribing group meetings are scheduled on a monthly recurring basis going forward and the action and implementation plan will continue to be developed and monitored via this group.</p> <p>EQIA Assessment: N/A</p>	
5.6	<p>Tirzepatide prescribing support information (for type 2 diabetes)</p> <p>The Committee considered a prescribing support document, to support Primary Care prescribing, for tirzepatide for treating type 2 diabetes (T2DM). Tirzepatide is recommended by NICE in TA924 for the treatment of T2DM.</p> <p>Tirzepatide is a long-acting GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist that increases insulin sensitivity and secretion, suppresses glucagon secretion, and slows gastric emptying. It is an alternative to GLP-1 receptor agonists (RA) for the treatment of adults with insufficiently controlled T2DM as per NICE NG 28 criteria for GLP-1 RA initiation, monitoring and continuation. Like the GLP-1 RA, prescribing will be done in primary care where eligible patients are mostly managed. Proposed traffic light status – GREEN.</p> <p>The recommended maintenance doses are 5, 10 and 15 mg depending on individual tolerance (the 7.5mg and 12.5mg strengths are not licensed maintenance doses but for titration alone). Adverse effects are more pronounced with increasing dose. Tirzepatide is currently only available in the UK in the pre-filled disposable injection device (KwikPen®) in 5mg and 10mg strengths. The other strengths are expected to become available in the coming months. Each KwikPen® device contains 2.4ml of solution (0.6ml per dose) and contains 4 doses of each specified strength.</p> <p>The Committee noted that:</p> <ul style="list-style-type: none"> • Optimise Rx messaging is being put in place to reinforce the prescribing recommendations for tirzepatide, for type 2 diabetes, and the need for regular review of patients. 	



No	Agenda Item	Action
	<ul style="list-style-type: none"> • This guidance is specifically for patients with type 2 diabetes, in line with NICE TA924, and is not applicable for patients for the management of obesity. There is a separate NICE TA under development for the obesity indication, which has an expected publication date of 29 May 2024. • The GLP1-RAs (liraglutide and semaglutide) used for obesity are restricted to specialist prescribing only (RED formulary traffic light) with tier 3 obesity service wraparound care to embed sustained lifestyle changes. • There are a number of private clinics in operation which are offering GLP1-RAs for weight loss – this sits entirely outside of the NHS and prescribing should not be transferred into the NHS. <p>Decision: The Committee approved the prescribing support information for tirzepatide for the management of type 2 diabetes.</p> <p>EQIA Assessment: Positive impact. According to the National Diabetes Audit (NDA) data 2022/23, there are 36.4% type 2 diabetes(T2DM) registrants in BLMK from Black, Asian and Minority Ethnic (BAME) communities. Those of BAME origin are likely to be diagnosed with T2DM at an early age and consequently, are disproportionately at greater risk of developing complications associated with T2DM.</p> <p>Availability of tirzepatide as an alternative to GLP-1 RA provides an additional treatment option for T2DM in this population as per NICE NG28. Where it is deemed clinically appropriate, it will help reduce health inequalities for this population. (NB: updated following receipt of E&D comments).</p> <p>BLMK ICB E and D Lead comment: Section 4 – No impact has been ticked - from my recollection there is a higher incidence of people from a BME background who are diagnosed with T2DM. This addition to the formulary will provide access to an additional treatment which indicates that it will have a positive impact, reducing health inequalities? If correct, can this please be documented on the form?</p> <p><i>Author's response:</i> section reviewed and updated in response to these comments.</p>	
5.7	<p>Asthma guidelines (adult)</p> <p>The Committee considered updated guidelines for the management of asthma in adult patients. The proposed guidelines reflect a change to existing recommendations and reflects international GINA (Global Initiative for Asthma) guidelines updated in 2023. NICE / BTS are expected to publish updated joint guidance in 2024. The All Wales Medicines Strategy Group (AWMSG) has also recently published an update to its adult asthma guidance which recommends the GINA approach.</p> <p>The updated guidelines include preferred and traditional treatment strategies. The GINA preferred treatment strategy uses 'as required inhaled corticosteroid (ICS) / formoterol inhaler' (also known as AIR or anti-inflammatory reliever) for the initial treatment step, instead of</p>	



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	<p>regular ICS + prn short acting beta agonist (SABA.) Then maintenance and reliever therapy (MART) with ICS / formoterol instead of ICS/LABA + prn SABA. The preferred treatment strategy sits alongside a 2nd line traditional pathway.</p> <p>The Committee noted and discussed the following additional points:</p> <ul style="list-style-type: none"> • The preferred strategy is based on evidence of reduced asthma exacerbations and hospitalisations and will be recommended for new patients and as an option for patients with uncontrolled asthma. • The preferred/GINA regimen approach is advocated by the primary care respiratory society. • The only inhaler that currently has an AIR licence is Symbicort Turbohaler 200/6, however an alternative MDI option (off-label use of Luforbec 100/6 inhaler) is included as an option for patients when needed. • Inhaler costs are similar at step 2 but increased at step one (approximately £52,000/year for new patients.) However, achieving asthma control saves £378 per patient/year across the ICS. Additional cost savings can be realised through increased use of Luforbec and Fobumix inhalers. • The guidance was circulated to the BLMK respiratory long-term conditions group, and feedback received has been incorporated into the version circulated to the APC. • The maximum number of puffs per day is not currently stated for the inhaler options in Step 1 of the GINA/preferred treatment regimen – this information is to be added. • Information about ethanol contained in some inhalers (see feedback from Equality & Diversity lead below) will be incorporated into the guidance. • Training and learning/up-skilling for prescribers and all members of the healthcare team who may see these patients, and for patients and carers, will be key to implementing the changes in the new guidance. • Secondary care will also be adopting this approach (though they are less likely to be seeing patients at the early stages / steps in the pathway). Urgent Treatment Centres (UTC) and out of hours GP service will need to be engaged to ensure that they are aware of the change in the Asthma guidance. • The guideline highlights more environmentally friendly inhalers. Improving control and reducing inhaler numbers is also greener care. <p>Decision: The updated adult asthma guidelines were approved with the amendments agreed above.</p> <p>EQIA Assessment: No impact. The revised asthma guidelines are a reflection of the current GINA guidelines. They are not mandatory, and clinicians should use their clinical discretion when using. The revised asthma guidelines refer to some pMDIs that contain alcohol. These pMDIs have been on formulary for some time. The level of ethanol is very small and less than the amount in a ripe</p>	<p>HMCG</p> <p>HMCG</p>



No	Agenda Item	Action
	<p>banana. Some religious groups may have concerns about ethanol being present in their medications. A statement within or separate to the guidelines may be necessary to raise awareness of the need to disclose ethanol content to patients where appropriate. Alternative ethanol free pMDIs are available where needed. (NB: information around alcohol added in response to E&D comment).</p> <p>BLMK ICB E and D Lead comment: Section 4 – the guidelines have been revised in-line with GINA guidelines. I understand the Salamol (not sure if there are others), contains a small amount of alcohol which some people may not wish to take if they knew this on religious grounds. Is there a mechanism of sharing this type of information so that religious/cultural considerations can take place? If there is, or it has been a consideration during the compilation of the updated guidance then please include in this section.</p> <p><i>Author's response:</i> section reviewed and updated in response to these comments, and information to be added to the guidance.</p>	
6.0	<p>NICE Guidance – from 23 November 2023 to 14 February 2024</p> <p>The following NICE Technology Appraisal Guidance (ICB Commissioned) have been published:</p> <ul style="list-style-type: none"> <p>Dupilumab for treating eosinophilic oesophagitis in people 12 years and over (terminated appraisal) Technology appraisal [TA938] Published: 07 December 2023 https://www.nice.org.uk/guidance/ta938</p> <p>APC action(s): none – terminated appraisal.</p> <ul style="list-style-type: none"> <p>Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes Technology appraisal guidance [TA943] Published: 19 December 2023 https://www.nice.org.uk/guidance/ta943</p> <p>Resource impact: to be calculated via resource impact template when costs available (framework prices, for cost-effective pricing, for hybrid closed loop (HCL) systems have not yet been published).</p> <p>NB: Access to hybrid closed loop systems will be through a 5-year phased roll out in line with NHS England's and NHS Wales' implementation plans. Hybrid closed loop systems will be commissioned via NHS England or NHS providers in line with the 5-year strategy. Not all pricing has yet been agreed with the manufacturers and work will be continuing to agree HCL prices in the new year.</p> <p>See also agenda item 8.1 for formulary subgroup recommendations regarding FreeStyle Libre 3.</p> <p>APC actions: initial discussions and implementation plan being agreed via the BLMK CGM working group.</p> <p>The Committee also noted that NICE has confirmed that TA151 (recommendations on insulin pumps for patients with type 1</p>	



No	Agenda Item	Action
	<p>diabetes) is still an active TA and would be used when people do not want/need an HCL. Note: TA151 has a higher HbA1c threshold than TA943, therefore is likely to be used less following the publication of TA943.</p> <ul style="list-style-type: none"> Empagliflozin for treating chronic kidney disease Technology appraisal guidance [TA942] Published: 20 December 2023 https://www.nice.org.uk/guidance/ta942 <p>Resource impact: approximately £5,000 per 100,000 population (£50,000 for BLMK) in 2024/25, rising to £27,000 per 100,000 population (£270,000 for BLMK) by 2027/28. There is an additional cost pressure as empagliflozin may be used in a similar, but broader, population to dapagliflozin (TA755)</p> <p>APC actions: to be added to the formularies (Green traffic light for the majority of patients) and information for clinicians produced to support prescribing – see also agenda item 5.3.</p> <ul style="list-style-type: none"> Targeted-release budesonide for treating primary IgA nephropathy Technology appraisal guidance [TA937] Published: 20 December 2023 https://www.nice.org.uk/guidance/ta937 <p>Resource impact: NICE do not expect this guidance to have a significant impact on resources (less than £8,800 per 100,000 population – approximately £88,000 for the BLMK population).</p> <p>APC actions: created and link added to formularies (RED traffic light)</p> <p>The following NICE Guidelines (NG) (Medicine related and ICB Commissioned) have been published / updated by NICE:</p> <p>Acne vulgaris: management NICE guideline [NG198] Published: 25 June 2021 Last updated: 07 December 2023 https://www.nice.org.uk/guidance/ng198 APC actions: to be reviewed and managed via the Medicines Safety Group.</p> <p>Cardiovascular disease: risk assessment and reduction, including lipid modification NICE guideline [NG238] Published: 14 December 2023 https://www.nice.org.uk/guidance/ng238 APC actions: for review via the CVD long-term conditions group. No actions at the current time.</p> <p>Bipolar disorder: assessment and management Clinical guideline [CG185] Published: 24 September 2014 Last updated: 21 December 2023 https://www.nice.org.uk/guidance/cg185 APC actions: implementation of valproate recommendations being reviewed via dedicated working group. On APC agenda for discussion (see agenda item 5.5).</p>	



No	Agenda Item	Action
	<p>Early and locally advanced breast cancer: diagnosis and management NICE guideline [NG101] Published: 18 July 2018 Last updated: 16 January 2024 https://www.nice.org.uk/guidance/ng101 APC actions: none – no changes to medicines’ guidance.</p> <p>Suspected sepsis: recognition, diagnosis and early management NICE guideline [NG51] Published: 13 July 2016 Last updated: 31 January 2024 https://www.nice.org.uk/guidance/ng51 APC actions: none – amendments relate to in hospital management only.</p> <p>The following COVID 19 related information has been produced/updated by NICE:</p> <p>COVID-19 rapid guideline: managing COVID-19 NICE guideline [NG191] Published: 23 March 2021 Last updated: 25 January 2024 https://www.nice.org.uk/guidance/ng191 APC actions: none – updates link to existing NICE guidelines.</p> <p>COVID-19 rapid guideline: managing the long-term effects of COVID-19 NICE guideline [NG188] Published: 18 December 2020 Last updated: 25 January 2024 https://www.nice.org.uk/guidance/ng188 APC actions: none – no changes to recommendations.</p> <p>The following NICE TAs are the commissioning responsibility of NHSE and are listed for information only:</p> <p>Decitabine–cedazuridine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable (terminated appraisal) Technology appraisal [TA932] Published: 23 November 2023 https://www.nice.org.uk/guidance/ta932 APC actions: none – terminated appraisal.</p> <p>Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies (terminated appraisal) Technology appraisal [TA933] Published: 29 November 2023 https://www.nice.org.uk/guidance/ta933 APC actions: none – terminated appraisal.</p> <p>Foslevodopa–foscarnidopa for treating advanced Parkinson’s with motor symptoms Technology appraisal guidance [TA934] Published: 29 November 2023 https://www.nice.org.uk/guidance/ta934 APC actions: created and link added to Formularies (RED traffic light) and additional text “Specialist only in line with NICE and NHS Commissioning Policy”.</p> <p>Idecabtagene vicleucel for treating relapsed and refractory multiple myeloma after 3 or more treatments (terminated</p>	



No	Agenda Item	Action
	<p>appraisal) Technology appraisal [TA936] Published: 30 November 2023 https://www.nice.org.uk/guidance/ta936 APC actions: none – terminated appraisal.</p> <p>Secukinumab for treating moderate to severe hidradenitis suppurativa Technology appraisal guidance [TA935] Published: 06 December 2023 https://www.nice.org.uk/guidance/ta935 APC actions: link added to Formularies (RED traffic light)</p> <p>Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer Technology appraisal guidance [TA939] Published: 13 December 2023 https://www.nice.org.uk/guidance/ta939 (NB: replaces NICE TA885) APC actions: links added to formularies (RED traffic light)</p> <p>Velmanase alfa for treating alpha-mannosidosis Highly specialised technologies guidance Reference number: HST29 Published: 13 December 2023 https://www.nice.org.uk/guidance/hst29 APC actions: none – no local use expected (highly specialised)</p> <p>Risdiplam for treating spinal muscular atrophy Technology appraisal guidance Reference number: TA755 Published: 16 December 2021 Last updated: 15 December 2023 In December 2023, the Medicines and Healthcare products Regulatory Agency approved a licence extension for risdiplam to include people of all ages. NICE updated the recommendation and information in section 2 to account for this extension to the marketing authorisation. APC actions: none</p> <p>Ravulizumab for treating AQP4 antibody-positive neuromyelitis optica spectrum disorder (terminated appraisal) Technology appraisal [TA941] Published: 20 December 2023 https://www.nice.org.uk/guidance/ta941 APC actions: link added to formularies (terminated appraisal)</p> <p>Ravulizumab for treating generalised myasthenia gravis (terminated appraisal) Technology appraisal [TA940] Published: 20 December 2023 https://www.nice.org.uk/guidance/ta940 APC actions: link added to formularies (terminated appraisal)</p> <p>Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer Technology appraisal guidance [TA944] Published: 10 January 2024 https://www.nice.org.uk/guidance/ta944 APC actions: Links added to formularies.</p>	



No	Agenda Item	Action
	<p>Sebelipase alfa for treating Wolman disease Highly specialised technologies guidance Reference number: HST30 Published: 10 January 2024 https://www.nice.org.uk/guidance/hst30 APC actions: none – no local use expected (highly specialised)</p> <p>Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer Technology appraisal guidance [TA946] Published: 17 January 2024 https://www.nice.org.uk/guidance/ta946 APC actions: links added to formularies.</p> <p>Treosulfan with fludarabine before allogeneic stem cell transplant for people aged 1 month to 17 years with non-malignant diseases (terminated appraisal) Technology appraisal [TA945] Published: 30 January 2024 https://www.nice.org.uk/guidance/ta945 APC actions: links added to formularies (terminated appraisal)</p> <p>Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments Technology appraisal guidance [TA947] Published: 31 January 2024 https://www.nice.org.uk/guidance/ta947 APC actions: created and link added to Formularies (RED traffic light)</p> <p>Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments Technology appraisal guidance [TA948] Published: 31 January 2024 https://www.nice.org.uk/guidance/ta948 APC actions: created and link added to Formularies (RED traffic light)</p> <p>Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over Technology appraisal guidance [TA949] Published: 07 February 2024 https://www.nice.org.uk/guidance/ta949 APC actions: none – no local use expected.</p> <p>Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over Technology appraisal guidance [TA950] Published: 07 February 2024 https://www.nice.org.uk/guidance/ta950 APC actions: created and link added to Formularies (RED traffic light)</p> <p>Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer Technology appraisal guidance [TA951] Published: 07 February 2024 https://www.nice.org.uk/guidance/ta951 APC actions: links added to formularies.</p>	



No	Agenda Item	Action
7.	<p>Medicines Safety update A Primary Care Medicines Safety Update and a Medicines Safety Group Update was presented to the Committee.</p> <p><u>Primary Care Medicines Safety Update</u></p> <p>This update focussed on the primary care response to the MHRA Drug Safety Updates and CAS alerts (November 2023 to January 2024). In particular:</p> <p>Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate (DSU, January 2024) Linked to formularies. Usage within BLMK already heavily restricted however the DSU is planned for discussion at the March AMR group to explore any further actions. There is now a PIL available via Ardens to support the new restrictions.</p> <p>The Committee discussed the guidance for prescribing fluoroquinolones in primary care for e.g. prostatitis, epididymo-orchitis for which fluoroquinolones were normally the first line treatment options – this is unlikely to change for primary care for this patient cohort. Prescribing in women (likely primarily for UTIs) does need to be reviewed and education provided.</p> <p>Secondary care trusts have gone through antimicrobial guidelines and moving fluoroquinolones to 3rd or 4th line. This will go to DTC for approval and shared with the regional AMS group thereafter.</p> <p>Potential contamination of some carbomer-containing lubricating eye products with Burkholderia cenocepacia - measures to reduce patient risk (CAS alert, December 2023) Linked to formularies. In primary care, an alert message has been created on OptimiseRx which will present if a carbomer product is newly prescribed or re-authorised for a patient coded as having CF. There is also a clinical report which can be found in Ardens. It was noted that patient numbers are low due to recent shortages of carbomer products.</p> <p>Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba) products (CAS alert, December 2023) Linked to formularies. BHFT and ELFT have produced a memo on this and have circulated Trust-wide to raise awareness. The memo will be shared with MSG.</p> <p>Shortage of GLP-1 receptor agonists (GLP-1 RA) update (CAS alert, January 2024) Linked to formularies. Temporary recommendation taken via FSG to enable patients on injectables (Victoza and Byetta) to switch to Rybelsus tablets (see agenda items 8.1 and 13.1 for more details).</p>	



No	Agenda Item	Action
	<p>The following DSUs and CAS alerts have been circulated and linked to the Formularies where appropriate for dissemination and sharing:</p> <p>Drug Safety alerts:</p> <ul style="list-style-type: none"> • E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme (November 2023). • Nirmatrelvir, ritonavir (Paxlovid ▼): be alert to the risk of drug interactions with ritonavir (November 2023). • Ozempic ▼ (semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products (November 2023). • Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions (December 2023). • Aripiprazole (Abilify and generic brands): risk of pathological gambling (December 2023). • Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors (January 2024). • Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age (January 2024). See also agenda item 5.5. <p>CAS alerts:</p> <ul style="list-style-type: none"> • Shortage of verteporfin 15mg powder for solution for injection (September 2023) • Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients (November 2023). See also agenda item 5.5. • Identified safety risks with the Euroking maternity information system (December 2023). No action required as not in use within BLMK ICS. • Influenza Season 2023/24: Use of antiviral medicines (December 2023). <p><u>Medicines Safety Group (MSG) Update</u></p> <p><u>Medication safety projects:</u></p> <p>Actimorph (morphine sulphate orodispersible tablets) – engagement to use project</p> <p>Plans to set up an Opioid Subgroup - currently in the process of gauging interest from relevant stakeholders. Engagement via posters (in development), amongst other workstreams relating to medicines safety around opioids, will be looked at by this group. It was noted that there is a growing appetite for use of Actimorph in secondary care, for both pain management and palliative care use. Plans to link</p>	



No	Agenda Item	Action
	<p>in the Opioid Stewardship group at MKUH and the Pain Management subgroup/Palliative Care consultants at BHFT to ensure a systemwide approach. There are some barriers to potentially introducing actimorph into secondary care, including the controlled drug status of actimorph (actimorph is a schedule 2 controlled drug, whereas morphine sulphate 10mg/5ml oral solution is a schedule 5 controlled drug).</p> <p>SystemOne local Formulary A local set of Formularies has been created and embedded within SystemOne BLMK wide to direct prescribers to sets of the most commonly prescribed medicines on Formulary. It is hoped this will aid Formulary adherence, reduce variation and prescribing errors and save prescribers time by having common medicines to hand in the list.</p> <p><u>MSO Regional update (East of England network)</u></p> <ul style="list-style-type: none"> • Drug interaction case review - significant drug interaction with atorvastatin and fusidic acid (patient also consuming large amounts of grapefruit) resulting in moderate harm to the patient. • Interaction between tramadol and warfarin – coroner has advised NHS England to warn prescribers about this interaction following the death of a patient. Previously the interaction was only listed in the BNF under warfarin, but this has recently been updated so that the interaction is also listed under tramadol. • Sharing of unlabelled insulin pre-filled pens on hospital wards – shared learning from across the region highlighting the risks associated with this practice. This learning originated in a trust outside of the BLMK area. • New high strength azathioprine 100mg and 75mg tablets now licensed and available (see also agenda item 8.1). <p>The Committee noted the medicines safety update.</p>	
8.	Formulary Update	
8.1	<p>Formulary Subgroup Recommendations The following recommendations were made by the Formulary subgroup at the February 2023 meeting:</p> <ul style="list-style-type: none"> • Glycopyrronium 1mg & 2mg tablets (Assicco brand) for sialorrhoea in children and adolescents (licensed) and adults (off-label). 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 (SpA formulary status). 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). Assicco was considered as a cost-effective brand of Glycopyrronium tablets – small patient numbers but significant saving potential. 	



No	Agenda Item	Action
	<p>Proposal: Add Assicco as the preferred tablet option for sialorrhoea 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, with active switching from generic tablets to realise the savings. <i>Cost impact of decision:</i> Cost saving approx. £58k if 100% switch.</p> <ul style="list-style-type: none"> • Freestyle Libre 3 (FSL3) real time continuous glucose monitoring device – best mechanism for supply. 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) it was brought to FSG to agree the best mechanism for prescribing and by whom. <p>Proposal: FSL3 prescribing via GP agreed under specialist advice (SpA traffic light) for the following groups:</p> <ul style="list-style-type: none"> ○ Existing patients on FSL3 to be transferred on to FP10. ○ New patients restricted to use with Hybrid Closed Loop systems (HCL). ○ Expand eligibility to allow FSL3 to be used in patients under 20 years of age (with or without HCL). ○ Agreement currently restricted to Bedfordshire Hospitals, with further discussions regarding financial arrangements and invoicing to be undertaken for Milton Keynes Hospital. <p>Benefits:</p> <ul style="list-style-type: none"> ○ Prevents high cost and unnecessary upgrade of patients from FSL2 to FSL3. ○ Children and young people will benefit from desirable features including a smaller, lighter wearable sensor and the ability to share real time glucose readings with parents/carers remotely. ○ More convenient for patients to obtain supply and reduced administrative burden on NHS Supply chain. ○ The ICB will realise VAT savings in the order of £66k per annum. ○ Usage can be monitored via EPACT2 reporting. <p>NB: FSL2 was concluded to be suitable for the majority of patients and upgrade to FSL3 is not necessary as FSL2 is also a rtCGM device following software update. Unnecessary upgrade would also result in a significant cost pressure due to the presence of a volume dependent rebate in operation for FSL2, which may be voided if large numbers of patients moved to FSL3. <i>Cost impact of decision:</i> VAT saving approx. £66k per annum however shift of budget from MKUH (arrangement currently in block) to the ICB is a cost pressure – TBC pending discussions with the Trust.</p> <ul style="list-style-type: none"> • 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 was 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 	



No	Agenda Item	Action
	<p>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.</p> <p>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.</p> <p><i>Cost impact of decision:</i> None expected. LES payments for SCGs currently under review – likely no impact on cost for this particular SCG.</p> <ul style="list-style-type: none"> • 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 considered that 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. <i>Cost impact of decision:</i> Protection of future budget through discouraged use of disproportionately high cost strengths, cost saving. • 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 by the Supreme Court. This means that there is no further barrier to the supply of generic apixaban. Recommendations: Due to the completion of the legal challenge and the significant unforeseen price reduction of apixaban and change in NHS England guidance: <ul style="list-style-type: none"> ○ 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). 	



No	Agenda Item	Action
	<ul style="list-style-type: none"> • <i>Cost impact of decision:</i> Predicted saving based on current prescribing of the apixaban price drop is £4.7M per annum for BLMK ICB. • Semaglutide (Rybelsus) temporary adjustment of Formulary position during period of injectable GLP1 agonist shortage. Following publication of the National Patient Safety Alert (NatPSA) relating to shortages of GLP-1 RAs, the medicines optimisation team proposed 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. Recommendations: <ul style="list-style-type: none"> ○ 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. ○ Existing patients on Victoza® (liraglutide) and Byetta® (exenatide) on repeat prescription – as per the NPSA alert 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. <p>The proposal was accepted, and it was agreed that a short switching guide to support prescribers would be beneficial. See agenda item 13.1).</p> <p><i>Cost impact of decision:</i> Cost neutral based on current pricing.</p> • Nutriprem Human Breast Milk Fortifier. This 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. 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. 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. Further exploration of the best mechanism of supply is needed and will be taken forward. <i>Cost impact of decision:</i> 8 patients per annum from MKUH, cost pressure £4000. Figures TBC from BHFT. No change at the current time while route of supply is investigated. 	



No	Agenda Item	Action
	<ul style="list-style-type: none"> Biosimilar insulins – Formulary alignment and mitigation against current shortage of Lantus. 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. 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. Recommendations: <ul style="list-style-type: none"> 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. 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 but where patients may be prescribed the biosimilar dose adjustment may be needed. <p><i>Cost impact of decision:</i> Cost saving with any increased use of Semglee instead of Lantus.</p> Cytisine 1.5mg tablets for smoking cessation (new product). Nicotine receptor partial agonist, complete treatment course of 25 days = £115. Proposed and accepted: Non-formulary pending review and discussion with Public Health. The APC noted that, since the Formulary Subgroup was held, NICE has published an exceptional review of cytisine as part of their considerations for NG209 “Tobacco: preventing uptake, promoting quitting and treating dependence”. NICE concluded that cytisine should be listed in the medicinally licensed product recommendations in NG209 as an option for people who smoke, but that “Topic expertise is required on whether cytisine is recommended to people who smoke as a product that is 'more likely to result in them successfully stopping smoking' (recommendation 1.12.7) or 'less likely to result in them successfully stopping smoking' (recommendation 1.12.8).” Minor amendments log – the minor amendments made to the formulary since the last meeting were noted. <p>Decision: The committee ratified the recommendations of the Formulary Subgroup.</p>	
8.2	<p>Wound Management Formulary Steering Subgroup Recommendations A report from the wound management subgroup meetings in January 2024 was presented to the Committee:</p> <p>Formulary Alignment and Development: Nothing to report – no proposals as the Group was not quorate.</p>	



No	Agenda Item	Action
	<p>Financial: High spend in one practice in MK has been investigated and results show that this was due to three patients needing expensive but effective and clinically appropriate dressings. ELFT spending is being looked at as some colleagues are using the incorrect account for ordering via NHSSC. This has now been resolved and spend will be monitored.</p> <p>Online formulary: The draft version of the Milton Keynes Practice Nurses formulary is being reviewed by TVNs from CNWL. Technical issues thus far have been resolved.</p> <p>The use of product samples (dressings/creams) from Reps on patients is not recommended as it cannot be guaranteed that products have been kept in an optimal storage condition and so the quality of the product cannot be assured. The position statement on the clinical use of product samples can be found on the Wound Formulary on Microguide. In some circumstances, a clinician may wish to use a product sample for trial purposes, and it would be at their discretion as to whether Rep-supplied products would be suitable for use on patients, taking into consideration appropriate governance and patient expectation.</p> <p>The Committee noted the report from the Wound Management Steering group</p>	
9.	Patient Group Direction Subgroup Recommendations	
9.1	<p>MK Urgent Care PGDs The following recommendations were made by the Patient Group Direction (PGD) subgroup – to approve the PGDs submitted for review and approval by the MK Urgent Care Service (MKUCS):</p> <p>The following PGDs were presented for approval with clinical changes:</p> <ul style="list-style-type: none"> • Levonorgestrel and Ulipristal for emergency contraception – switched to national templates. • Clotrimazole cream – addition of extra adverse effects: <ul style="list-style-type: none"> ○ Clotrimazole 1% cream for uncomplicated balanitis. ○ Clotrimazole 2% cream & 500mg vaginal tab for uncomplicated vaginal candida / candidiasis in women. <p>The following PGDs were presented for approval with no clinical changes:</p> <ul style="list-style-type: none"> • Adrenaline 1 in 1000 injection for emergency treatment of anaphylaxis. • Chloramphenicol eye preparations for infective conjunctivitis & blepharitis in children aged 1 month to under 2 years. • Codeine 30mg tablets for moderate pain. • Salbutamol for adults & adolescents aged 13 years and over for the relief of acute exacerbations and severe attacks of asthma and emergency relief of breathlessness in COPD patients. 	



No	Agenda Item	Action
	<ul style="list-style-type: none"> • Salbutamol for bronchodilator responsiveness testing in asthma and COPD in adults. • Salbutamol for children aged 2-12 years inclusive for the relief of acute exacerbations and severe attacks of asthma. • Trimethoprim for the treatment of lower UTI in lien with national and local antimicrobial guidance in children aged 6 months – 16 years. <p>The following, new, PGD was presented for approval by the APC:</p> <ul style="list-style-type: none"> • Apixaban 5mg tablets for adults awaiting diagnostic confirmation of DVT – new PGD (reviewed by the MKUH Anticoagulant Lead). Historically the MKUCS has used dalteparin as an initial treatment for patients who are awaiting diagnostic confirmation of a potential DVT, but the service wish to move to apixaban instead. The PGD has therefore been developed to support this change. <p>It was highlighted that GP practice anticoagulation hubs may still be using dalteparin in these patients awaiting diagnostic confirmation of DVT. Further discussion to take place around Local Enhanced Services for anticoagulation to understand if practice is aligned between primary and secondary care.</p> <p>The Committee noted that the expiry date of the MKUCS Benzylpenicillin PGD has been extended by 3 months as the review of the national template has been delayed.</p> <p>Decision: The Committee ratified the recommendations of the PGD subgroup and approved the new PGD for apixaban.</p>	MD/JC
10.	<p>Antimicrobial Resistance Update</p> <p>There have been no meetings of the antimicrobial resistance system wide group since the last APC meeting, however the latest primary care antibiotic use reports were presented to the Committee for information.</p> <p>The data presented highlighted that, whilst still high, total antibiotic usage is starting to fall, both nationally and within BLMK, following the group A strep outbreak a year ago.</p> <p>The Committee noted the antimicrobial stewardship update.</p>	
All other papers (from this point in the agenda) are for noting/information by the Committee		
11.	East of England Priorities Advisory Committee (EoEPAC) – items for noting/approval	
11.1	EoEPAC Meeting Notes – September 2023 The committee noted the minutes for information.	
12.	Bedfordshire, Luton and Milton Keynes Local Prescribing Committee Minutes. The Committee noted the following minutes for information.	




No	Agenda Item	Action
12.1	Minutes of the Bedfordshire Hospitals Foundation Trust Drug and Therapeutics Committee (DTC) – November 2023	
12.2	Minutes of the Milton Keynes Hospital Prescribing & Medicines Governance Committee (PMGC) – December 2023	
12.3	Minutes of the BLMK Formulary Subgroup – November 2023	
12.4	Minutes of the BLMK Wound Management Formulary Steering Group – November 2023	
12.5	Minutes of the BLMK Medicines Safety Group – November 2023	
12.6	Minutes of the ELFT Medicines Management Committee – November 2023	
12.7	Minutes of the Cambridgeshire Community Services Medication Safety and Governance Group – November 2023	
12.8	Minutes of the CNWL Trustwide Medicines Optimisation Group (MOG) – September and December 2023	
12.9	Minutes of Circle/MSK Medicines Management Committee – November 2023	
13.	Papers for information / ratification	
13.1	<p>Chair’s action – oral semaglutide switching document In response to the recent National Patient Safety Alert - NatPSA 2024- GLP-1 receptor agonists it was agreed at the Formulary Subgroup meeting, held on 06 February 2024, that the formulary statuses of the GLP-1 receptor agonists (RAs) will be amended as follows:</p> <p>Oral semaglutide (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.</p> <p>It was proposed and agreed that a short guide to aid prescribers switching patients from injectable GLP-1 RAs to oral semaglutide should be developed. Due to the immediate need to issue the guidance, Chair’s approval was sought to allow the document to be circulated prior to the APC meeting. The Committee was therefore asked to note and ratify the guidance document previously approved via Chair’s action.</p> <p>Decision: The Committee noted and ratified the oral semaglutide switching document.</p>	
14.	<p>Any other business</p> <ul style="list-style-type: none"> Title of “Treatment and Prevention of Migraine / Tension Type Headache” approved at APC in December 2023: a query has arisen about the inclusion of tension type headache in the title and text of the guideline as the contents of the guideline 	



No	Agenda Item	Action
	<p>relate to the management of migraine only. The exception to this is the recommendations around simple analgesics at the beginning of the guideline. It was therefore proposed that the document is amended and updated to remove reference to tension-type headache – this was agreed by the Committee.</p> <ul style="list-style-type: none"> • BLMK Medicines website – timeframe for 'go live' of the updated website (there is currently a content freeze whilst migration to the new website is facilitated)? It was confirmed that it is planned for the new website to be live by the end of the week (by Friday 1st March). 	
15.	<p>Future Dates for BLMK APC 2023 / 2024 Meetings (all to be held from 12:30-15:00 via Microsoft Teams):</p> <p>Wednesday 1st May 2024 Wednesday 3rd July 2024 Wednesday 25th September 2024 Wednesday 4th December 2024</p>	

Approval of minutes:

Chair: Dr Muhammad Nisar

Signed: 

Date: 2 May 2024

Appendix 1 – Approved 06 February 2024 Formulary Subgroup Minutes:



FSG Minutes Final
February 2024.pdf

