BEDFORDSHIRE, LUTON AND MILTON KEYNES AREA PRESCRIBING COMMITTEE

Meeting Notes

Date: 06 December 2023
Time: 12:30 – 15:00
Venue: Microsoft Teams

Attendees:

Name	Initial	Role
Dr Muhammad Nisar	MN	Chair (Medical Representative, Bedfordshire Hospitals NHS Trust)
Yolanda Abunga (until 14:10)	YA	CCS Pharmacy Representative (Community Services Pharmacist, Beds and Luton)
Mojisola Adebajo (from 12:40)	MA	Place Based Lead Pharmacist – Luton
Reginald Akaruese	RA	CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes)
Dr Marian Chan	MC	Medical Representative, Bedfordshire Hospitals NHS Trust
Candy Chow	CC	Chair of Wound Care Group
Janet Corbett	JC	Milton Keynes Hospital Pharmacy Representative (Pharmacy Programme Manager, Milton Keynes Hospital)
Dr Dush Mital	DM	Medical Representative, Milton Keynes Hospital
Naomi Currie	NC	Place Based Lead Pharmacist - Bedford
Dupe Fagbenro	DF	ELFT Pharmacy Representative (Deputy Chief Pharmacist (Luton and Bedfordshire), ELFT)
Fiona Garnett	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
Dr Kate Randall (from 12:50)	KR	Place Based Lead GP – Central Bedfordshire
Dr Mitan Sarkar	MS	Place Based Lead GP - Luton
Dr Jonathon Walter	JWa	Place Based Lead GP – Milton Keynes

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 Jenny Wilson	JWi	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:		
Rafal Ali	RA	Commissioning Pharmacist, BLMK ICB
Sandra McGroarty	SMcG	Commissioning Pharmacist, BLMK ICB
Dr Joy Muttika	JM	Medical Representative, Keech Hospice
Andrew Tse	AT	Milton Keynes Hospital Pharmacy Representative (Medication Safety Officer, Milton Keynes Hospital)
Sharon Wilmore	SW	PA to MOT, BLMK ICB (admin support)
Nikki Woodall	NW	Lead Medicines Optimisation Technician, BLMK ICB
Dr Sneha Patel (for agenda item 5.5)	SP	Consultant Haematologist, Bedfordshire Hospitals Trust
Priya Shah (for agenda item 5.5)	PS	Macmillan Pharmacist, Bedfordshire Hospitals Trust
Funmi Balogun (for agenda item 14.2)	FB	Community Pharmacy Integration Lead, BLMK ICB

Apologies:		
Nicola Ainsworth	NA	Consultant in Public Health
Sally Cartwright	SC	Consultant in Public Health
Helen Chadwick	HC	Milton Keynes Hospital Pharmacy Representative (Chief Pharmacist, Milton Keynes Hospital)
Taiya Large	TL	Formulary and Medicines Safety Pharmacist BLMK ICB
Tsana Simmonds	TS	ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton)

No	Agenda Item	Action
1.	**Welcome, Introductions and Apologies** The Chair welcomed everyone to the meeting. Apologies were received and noted as above. The meeting was confirmed as quorate. The Chair thanked Gemma McGuigan, who is moving to a new role, for her long service to the Committee and the legacy Bedfordshire & Luton Joint Prescribing Committee. The Chair welcomed Dr Sneha Patel, Priya Shah and Funmi Balogun to the meeting.	

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2.	**Declarations of Interest** The Chair invited the members to reconfirm their current declarations on the Register of Interests and advise of any new declarations. All members confirmed their declarations were accurate and up to date. The Chair invited members to declare any declarations relating to matters on the agenda. All other members confirmed they have no declarations in relation to matters on the agenda.	
3.	**Minutes of 27 September 2023 APC meeting** The minutes of the meeting held on 27 September 2023 were approved.	
4.	**Matters Arising**	
4.1	**Feedback on miscellaneous actions not included on the agenda from APC meetings**	
4.1.1	**Shared care patient information leaflet** Leaflet to be introduced into practice with BHFT Rheumatology and feedback sought from patients to 'test' the patient acceptability and accessibility of the leaflet. **Update 09/11/23** – the trial introduction of the leaflet has been delayed due to capacity/staffing issues in the trust, but it is hoped that it will commence shortly. This is an ongoing action.	MC
4.1.2	**Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction** Prescribing support information to be produced to aid primary care prescribers. **Update 22/11/23** – on December agenda for consideration – see agenda item 5.1 (to incorporate empagliflozin for the same indication). It was proposed and agreed that the action could be closed.	Close
4.1.3	**Patient Information Leaflets (PILs)** To feed back to NA the outcome of September APC discussion on the proposal for a policy to be developed regarding the production of PILs. **Update 28/09/23** – NA to work on developing the policy on PIL development, with an aim to bring it to February 2024 APC for consideration (added to APC workplan). It was proposed and agreed that the action could be closed.	Close

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4.1.4	**Severe psoriasis pathway update** Title to be amended to read 'standard systemic treatments', and wording around consideration via the IFR route to be updated as agreed at the September meeting. **Update 05/10/23** – wording updated, pathway finalised and uploaded onto the Medicines website. It was proposed and agreed that the action could be closed.	Close
4.1.5	**Crohn's pathway update** To be updated with the changes discussed at the meeting regarding Individual Funding Requests. **Update 12/10/23** – wording updated, pathway finalised and uploaded onto the Medicines website. It was proposed and agreed that the action could be closed.	Close
4.1.6	**Rheumatology high cost drug pathways** Wording around Individual Funding Requests to be updated as agreed at the meeting. **Update 12/10/23** – wording updated, pathway finalised and uploaded onto the Medicines website. It was proposed and agreed that the action could be closed.	Close
4.1.7	**Migraine high cost drug treatment pathway** Wording around Individual Funding Requests to be updated as agreed at the meeting. **Update 24/10/23** – wording updated, pathway finalised and uploaded onto the Medicines website. It was proposed and agreed that the action could be closed.	Close
4.1.8	**Hypertension patient information leaflet** To confirm whether guidance / information on low blood pressure and falls is built into the care plan for HTN within S1. **Update 16/11/23** – there is currently no wording in relation to hypotension on the S1 template - MD to work with S1 to have this added in. It was proposed and agreed that the action could be closed.	Close
4.1.9	**Guideline for Treatment and Prevention of Migraine / Tension-Type Headache** Document to be updated to remove domperidone and provide guidance on the best time for triptans to be taken (when the first aura symptoms are experienced, or at the start of the headache). **Update 16/10/23** – domperidone has been removed from the guideline and information added to the document to confirm that triptans should be taken at the onset of headache, not aura. On December agenda for consideration (see agenda item 7.1). It was proposed and agreed that the action could be closed.	Close
5.	**Items for consideration at meeting**	
5.1	**SGLT2i for treating chronic heart failure with preserved or mildly reduced ejection fraction prescribing guidance** At the July APC meeting dapagliflozin was approved for primary care initiation for people with Heart Failure with Preserved Ejection Fraction (HFpEF). At the meeting it was requested that prescribing	

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	guidance was developed to support GPs and other primary care health professionals to take on prescribing. Since then, a NICE TA for empagliflozin for the same indication (TA929) has been published. Guidance has been developed, which has been adapted from Bedfordshire NHS Trust SGLT2 Prescribing in Heart Failure Pathway, NICE TA902 & TA929 and respective SPCs for Dapagliflozin and empagliflozin. Input was also sought from the diabetes specialist teams. The document includes guidance on: • Renal thresholds for each medicine. • Contraindications. • Use with other meds which can impact volume status of the patient. • Links to patient information leaflets, which have been produced by the manufacturers, which may be shared with patients. • Sick day rules / counselling. • Diabetic ketoacidosis. • Important side effects and additional patient counselling (including Fournier's gangrene). **Decision**: The Committee approved the prescribing guidance. **EQIA Assessment:** No impact expected as the guidance does not exclude patient on the basis of any of the protected characteristics. **BLMK ICB E and D Lead comment:** Section 4 Rationale – suggest including: *this is an additional treatment choice and aims to improve access to all at primary care stage, reducing health inequalities.*	
5.2	**Antimicrobial guideline update** The Committee was presented with an update to the BLMK Primary Care Antimicrobial Prescribing Guidelines for consideration. Following the publication of new/updated NICE guidelines and Clinical Knowledge Summaries the following changes have been made: • Otitis media: Phenazone / Lidocaine (Otigo) eardrops added as an additional topical option for the symptomatic relief of otitis media where oral antibiotics are not recommended. A link to the NICE guideline: 'Otitis media with effusion in under 12s', published in August 2023, has also been added. It was confirmed that if treatment with antibiotics is required, oral antibiotics should be given. Topical antibiotics are not indicated. Confirmation was requested on whether it is suitable to use Otigo ear drops in patients who may have a perforated tympanic membrane, or who have grommets in situ – to be confirmed. • Otitis externa: Dexamethasone / Neomycin / Acetic Acid (Otimize) added as an additional option for the management of Otitis externa where topical antibacterials are required. Otomize spray is green on both the Bedfordshire/Luton and	NC

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	MK formularies. This addition reflects current practice and is in line with Ardens templates and NICE CKS advice. Ciprofloxacin ear drops will also be added to this section as an additional treatment option, as an alternative to topical aminoglycosides. • Lower respiratory tract infections: a link to new NICE guidance on the management of acute respiratory infection in over 16s (NG237) has been added to the guidelines for reference. The content of the NICE guidance does not contradict advice already contained within the antimicrobial guidelines around severity assessment or treating those at higher risk of deterioration presenting with acute cough or suspected CAP. **Decision**: The Committee approved the updated antimicrobial guidelines **EQIA Assessment:** N/A in line with NICE / national guidance	NC
5.3	**Osteoporosis Guideline Update** Strontium was previously in use across BLMK but has not been available in the UK since it was withdrawn from the market in 2017. More recently, Aristo Pharma have relaunched strontium, with associated risk minimisation materials including a patient alert card and a prescriber guide/checklist. The re-launch has led to a request from specialists to add strontium back onto the local joint formularies (currently non-formulary in Beds & Luton; remained on the formulary at MK however product has not been available until recently). Following discussion at the formulary subgroup, it was agreed that in principle, strontium (Aristo brand) could be re-instated to both local joint formularies as a treatment option, restricted to use where all other options have failed or are unsuitable. The proposed formulary status was allocated as SpA, i.e. specialist initiation/recommendation and GP continuation. It was noted that the MHRA issued guidance in 2014 which states that patients' risk of developing cardiovascular disease should be assessed before starting treatment. Treatment should not be started in people who have or have had: ○ ischaemic heart disease ○ peripheral arterial disease ○ cerebrovascular disease ○ uncontrolled hypertension AND cardiovascular risk should be monitored every 6-12 months. The BLMK osteoporosis guideline has therefore been updated to include strontium ranelate. Information has been added to the relevant sections of the document, with no changes to algorithm B (which relates to corticosteroid induced osteoporosis). Additional text has also been added to highlight rare, but serious, skin reactions which have been reported with Strontium; circumstances in which treatment with strontium should be suspended / stopped; and additional information regarding venous thromboembolism.	

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	In addition, the section on page 15 previously entitled 'counselling points' has been renamed as 'Additional Prescribing Information' and information has been added including links to the denosumab shared care guideline and the strontium Patient Alert Card and Prescriber Guide and Checklist. The following points were discussed: • Strontium is a long-term treatment – no drug holiday as you have for bisphosphonates. • Very few patients are expected to be started on strontium, as it is a last line treatment for osteoporosis. • GPs confirmed in principle that they would be able to do the cardiovascular risk assessments for strontium (as per MHRA advice), however further information and guidance needed on what this should consist of and whether there are any specific cut offs at which treatment should be stopped, advice & guidance sought, or patients referred back to secondary care. • Formulary traffic light status for strontium was discussed, with the possibility of shared care guidance or a prescribing fact sheet raised. No decision was reached, and further work is required. • There is less information contained in the guideline on secondary care only medicines such as romosozumab and teriparatide. This is because the guideline is intended for use by primary care clinicians. • It would be useful to include further information to highlight to GPs when to refer to secondary care for consideration of an alternative treatment. Concerns were raised that some patients may be being undertreated (with bisphosphonates) in primary care. • Education is needed for primary care clinicians, alongside updated Optimise Rx messaging, to highlight that patients at high risk of fracture need to be referred to secondary care. • Counselling points and links to patient information leaflets e.g. those produced by the Royal Osteoporosis Society to be added. **Decision**: The updated guidance was not approved as further work and clarification, as detailed above, is required. A working group is to be formed to take this forward. **EQIA Assessment:** Positive impact: The inclusion of strontium for restricted indications will allow clinicians the ability to offer treatment to a small group of patients who otherwise would be unable to receive treatment. Potential negative impact: The inclusion of strontium onto the formulary requires agreement between primary and secondary care as to who will be responsible for the ongoing cardiovascular risk monitoring. If an agreement is not agreed regarding who is doing the monitoring, then strontium will not be able to be used and this would	SMcG

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	have a negative impact on the small group of patients who could potentially benefit from treatment. **BLMK ICB E and D Lead comment:** 1. Section 4 Potential negative impact – Is there any evidence to suggest a disproportionate impact on one or more protected characteristics due to, for example, a higher incidence of osteoporosis in specific people? If not, then this doesn't need to be in the equality section. 2. You may wish to include something around providing the patient alert card in accordance with the accessible information standard or discussed with the patient in a way that is appropriate to them. **Author's response:** the assessment has been updated accordingly.	
5.4	**Linezolid prescribing guidance** The existing Bedfordshire & Luton linezolid prescribing information for primary care prescribers has been reviewed as it had reached its review date. There are minimal changes to the clinical content as the summary of product characteristics is largely unchanged since the last update. However, it was noted that the formulary status of linezolid is different across BLMK with RED traffic light in Milton Keynes and SpA designation in Bedfordshire/Luton. Each acute trust has expressed a preference to retain the existing traffic light designation and therefore the Committee was asked to agree the formulary status(es) going forward and to approve the updated prescribing guidance. The Committee discussed and agreed SpA designation on both formularies, achieving formulary alignment and enabling prescribing in primary care where appropriate. A small audit of primary care prescribing has been carried out – prescribing was found to be relatively low, and in line with microbiology results and microbiologist recommendation. The current wording on the Bedfordshire & Luton formulary entry for linezolid was discussed as it was identified to be confusing with SpA traffic light status, but a comment in the text stating "do not prescribe on FP10". It was clarified that the latter statement applies to hospital prescriptions only, which should be issued from the hospital pharmacy and not prescribed on a FP10HP prescription. The wording on the formulary entry will be reviewed and updated. **Decision**: The Committee approved the prescribing guidance and agreed SpA Formulary status for linezolid. **EQIA Assessment:** Impact depends upon APC decision: Current situation – formulary status differs between the two formularies. MK – RED and Beds / Luton – SpA. If linezolid is an appropriate option in MK patients will present at the SDEC and be issued a prescription. In Beds / Luton current situation would be consultant microbiologist recommendation via phone and GP can prescribe based on this recommendation. There are therefore currently differences in access arrangements.	NC/AG

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	If formulary status changes to RED for Beds / Luton – there would need to be pathways in place to ensure patients who required linezolid could receive this treatment in a timely manner. Limits access to patient who have previously been able to obtain this medicine. If formulary status change to SpA for both formularies this gives the option of prescribing in primary care for MK – the clinical discretion of microbiology would be followed, and appropriate Optimise RX messages can be put in to ensure prescribers are directed to call microbiology before issuing a prescription. This would improve access where indicated / recommended by the specialist. **BLMK ICB E and D Lead comment:** Section 4 Impacts – Option 1. Suggest adding "Potentially leading to health inequalities across the geography." Option 2. Suggest adding "Potentially leading to increasing health inequalities in groups less likely to attend secondary care in Beds and Luton." Option 3. Suggest adding "Potentially leading to reduced health inequalities and better outcomes across the geography." **Author's response:** the assessment has been updated accordingly.	
5.5	**Peginterferon for the treatment of polycythaemia vera (PV) and essential thrombocythaemia (ET)** The Committee was presented with a business case requesting the addition to the Bedfordshire/Luton formulary of Peginterferon alfa-2a (PegIFN alfa-2a) for the treatment of the myeloproliferative neoplasms (MPNs): polycythaemia vera (PV) and essential thrombocythaemia (ET). The treatment is for a small cohort of MPN patients. Past requests for PegIFN alfa-2a have been submitted via the IFR route and have been predominantly for MPN patients planning a pregnancy as hydroxycarbamide cannot be used in this setting due to being teratogenic. Additionally, PegIFN alfa-2a is available as an MPN treatment option, in specific clinical circumstances, across London hospitals and has been approved by the Hertfordshire Medicines Management Committee. Patients initiated in London hospitals often prefer for their treatment to be managed locally so inclusion of PegIFN alfa-2a for this indication on the formulary needed to be reviewed and discussed. It has also been in use at MKUH for a number of years, in accordance with Thames Valley cancer network guidance. It was noted that MPN is classified as a rare disease with around 520 cases of MPN in the UK per year. PV and ET can transform into myelofibrosis or acute myeloid leukaemia. MPNs generally remain stable or progress quite slowly and the aim of treatment is to manage blood counts and thereby reduce symptoms and the risk of thrombotic complications such as DVT, PE, stroke and heart attack.	

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	ICBs are responsible for the commissioning of services for haematological cancers with the exception of radiotherapy and chemotherapy. PegIFN alfa-2a was proposed as a treatment option for MPN (PV and ET) patients in the following circumstances: • As a second line treatment option following hydroxycarbamide where hydroxycarbamide is ineffective, contraindicated or not tolerated. • As a first line treatment option for younger patients (< 40 years age), patients that are pregnant or considering pregnancy. • For patients with aquagenic pruritus uncontrolled by hydroxycarbamide. PegIFN alfa-2a is more expensive than the hydroxycarbamide, but offers an alternative where patients are unsuitable, or have not responded to, hydroxycarbamide in line with the criteria above. The additional cost is expected to be approximately £9.3k rising to £23.4k by year 5. **Decision**: The Committee approved the use of PegIFN alfa-2a for polycythaemia vera (PV) and essential thrombocythaemia for the specific patient groups outlined above. **EQIA Assessment:** No impact. PegIFN alfa-2a has the advantage of being non-leukaemogenic and non-teratogenic. **BLMK ICB E and D Lead comment:** Impacts: Suggest: This change aims to improve access of this treatment as first line in younger patients who may be pregnant or considering pregnancy. This addition would reduce a current inequality where it is available in one Trust but not another. **Author's response:** the assessment has been updated accordingly.	
6.0	**NICE Guidance – from 14th September to 22nd November 2023** **The following NICE Technology Appraisal Guidance (ICB Commissioned) have been published:** • **Bimekizumab for treating active psoriatic arthritis** Technology appraisal guidance [TA916] Published: 04 October 2023 https://www.nice.org.uk/guidance/ta916 **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). This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Bimekizumab works in a similar way to ixekizumab and secukinumab and would be offered to the same population.	

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	APC actions: created and link added to Formularies (RED traffic light). Psoriatic Arthritis Treatment Pathway updated (see agenda item 7.5). • **Bimekizumab for treating axial spondyloarthritis** Technology appraisal guidance [TA918] Published: 11 October 2023 https://www.nice.org.uk/guidance/ta918 **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). This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Bimekizumab works in a similar way to ixekizumab and secukinumab and would be offered to the same population. **APC actions:** link added to Formularies (RED traffic light). Ankylosing Spondylitis/Non-radiographic Axial Spondyloarthritis Treatment Pathway updated (see agenda item 7.4). • **Rimegepant for treating migraine** Technology appraisal guidance [TA919] Published: 18 October 2023 https://www.nice.org.uk/guidance/ta919 **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). This is because rimegepant is a further treatment option and is for use after other options have been tried or are contraindicated or not tolerated. **APC actions:** To be added to both joint Formularies with GREEN traffic light status. Additional text to be added to the Formularies to highlight the appropriate place in therapy (following failure of at least 2 triptans or if triptans are contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough). • **Tofacitinib for treating active ankylosing spondylitis** Technology appraisal guidance [TA920] Published: 18 October 2023 https://www.nice.org.uk/guidance/ta920 **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). This is because the technology is a further treatment option and the overall cost of treatment will be similar. **APC actions**: link added to Formularies (RED traffic light). Ankylosing Spondylitis/Non-radiographic Axial Spondyloarthritis Treatment Pathway updated (see agenda item 7.4).	AG/JC

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	• **Daridorexant for treating long-term insomnia** Technology appraisal guidance [TA922] Published: 18 October 2023 https://www.nice.org.uk/guidance/ta922 **Resource Impact:** NICE expect this guidance to have a resource impact of approximately £10,000 per 100,000 population, £100,000 for the BLMK population – in 2023/24; rising to approximately £56,000 per 100,000 population, £560,000 for the BLMK population in 2027/28. The Committee noted and discussed the following key points: • Daridorexant is only recommended for the treatment of long-term insomnia if Cognitive Behavioural Therapy for insomnia (CBTi) has been tried but not worked, is not available or is unsuitable. • CBTi is available across BLMK, provided by 3 different Talking Therapies providers for Bedfordshire, Luton and Milton Keynes respectively. • The providers report CBTi to be an evidence-based intervention with good success rates. Patients may either self refer or be referred by their GP/other healthcare professional. • The availability of CBTi may not be widely known and therefore the information regarding the Talking Therapies providers will be shared with the Committee post-meeting and will also be shared wider in the Primary Care Bulletin, to raise awareness. • Concerns were raised that patients may not engage well with CBTi and that prescribing could escalate quickly as a result of patients preferring the option of taking medication rather than committing to engage with a course of CBTi. • Discussions from the ELFT NICE implementation group will be fed back to ensure a joined up approach. GREEN formulary status was proposed and agreed to be the appropriate designation, with the 'restricted' symbol applied on the formularies and wording from the NICE TA to be added to highlight the recommendations regarding CBTi being the first line treatment of choice. Optimise Rx messages will also be put in place to support appropriate prescribing, in accordance with the NICE recommendations. **APC actions**: to be added to both formularies with GREEN restricted traffic light status. Supportive Optimise messaging to be developed and additional information around the NICE TA requirements on CBTi to be added to the formulary entries. • **Tirzepatide for treating type 2 diabetes** Technology appraisal guidance [TA924] Published: 25 October 2023 https://www.nice.org.uk/guidance/ta924 **Resource Impact:** the NICE resource impact template indicates that	AG DF TL AG/JC

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	there may not be a significant resource impact from this guidance. This is because it is another treatment option, alongside existing GLP1 agonists (GLP1-RAs), and there is currently high usage of GLP1-RAs within BLMK. The Committee noted that tirzepatide is a long-acting dual GIP and GLP-1 receptor agonist and trials have demonstrated better results than with GLP1 agonists. The existing GLP1 agonists have GREEN traffic light status, with prescribing support information available, and it was proposed that the same approach should be adopted for tirzepatide. Specialists have been consulted for their views and they agreed with this approach. The Committee agreed that GREEN traffic light status is appropriate and that the supporting materials would be welcomed. **APC actions**: To be added to both formularies with GREEN traffic light designation. Prescribing supporting information to be developed and brought to next APC meeting in February 2024. • **Mirikizumab for treating moderately to severely active ulcerative colitis** Technology appraisal guidance [TA925] Published: 25 October 2023 https://www.nice.org.uk/guidance/ta925 **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). This is because mirikizumab is a further treatment option and the overall cost of treatment for this patient group will be similar. **APC actions:** created and link added to Formularies (RED traffic light). Ulcerative Colitis Pathway updated (see agenda item 7.3). • **Baricitinib for treating severe alopecia areata** Technology appraisal guidance [TA926] Published: 25 October 2023 https://www.nice.org.uk/guidance/ta926 **Resource impact:** none – not recommended **APC actions:** link added to formularies (not recommended) • **Ranibizumab for treating diabetic macular oedema** Technology appraisal guidance [TA274] Published: 27 February 2013 Last updated: 26 October 2023 https://www.nice.org.uk/guidance/ta274 **Resource impact:** no additional impact – technology already in use **APC actions:** none • **Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction** Technology	AG/JC MA

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	appraisal guidance [TA929] Published: 01 November 2023 https://www.nice.org.uk/guidance/ta929 **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). This is because the technology is a further treatment option, is available at the same price as dapagliflozin and clinical outcomes are expected to be similar. **APC actions:** link added to formularies. Formulary entries to be updated to reflect agreed GREEN traffic light status for this indication. Prescribing support information has been developed (see agenda item 5.1) – link to be added to both formularies. **The following NICE Guidelines (NG) (Medicine related and ICB Commissioned) have been published / updated by NICE:** **Intrapartum care** NICE guideline [NG235] Published: 29 September 2023 https://www.nice.org.uk/guidance/ng235 (NB: replaces NICE CG190 'Intrapartum care for healthy women and babies') **APC actions:** none – new medicines' related recommendations relate to secondary care only. **Urinary incontinence in neurological disease: assessment and management** Clinical guideline [CG148] Published: 08 August 2012 Last updated: 02 October 2023 https://www.nice.org.uk/guidance/cg148 **APC actions**: none – updates relate to cancer pathway referrals only. **Thyroid disease: assessment and management** NICE guideline [NG145] Published: 20 November 2019 Last updated: 12 October 2023 https://www.nice.org.uk/guidance/ng145 **APC actions:** none – updates refer to interpretation of thyroid function tests only. **Stroke rehabilitation in adults** NICE guideline [NG236] Published: 18 October 2023 https://www.nice.org.uk/guidance/ng236 (NB: replaces NICE CG162 'Stroke rehabilitation in adults'). **APC actions:** none **Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management** NICE guideline [NG237] Published: 31 October 2023 Last updated: 16 November 2023 https://www.nice.org.uk/guidance/ng237 **APC actions**: link added to BLMK antimicrobial guidelines (see agenda item 5.2). **Pneumonia in adults: diagnosis and management** Clinical guideline [CG191] Published: 03 December 2014 Last updated: 31 October 2023 https://www.nice.org.uk/guidance/cg191	AG/JC

No	Agenda Item	Action
	APC actions: see above (NG237) **Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer** Clinical guideline [CG164] Published: 25 June 2013 Last updated: 14 November 2023 https://www.nice.org.uk/guidance/cg164 **APC actions:** none at the current time – it was noted that the update to the guideline in relation to anastrozole for breast cancer prevention does not change previous guidance contained in CG164 (in the November 2023 update, NICE removed the off-label warning for anastrozole in their recommendations on chemoprevention for women at moderate or high risk of breast cancer, in line with the MHRA licence variation). The Committee discussed the use of anastrozole for the chemoprevention of breast cancer and it was noted that breast cancer specialists do not see these patients. There is a family history clinic in Luton and a genetics clinic in Oxford to which patients can be referred for assessment of risk and consideration of potential treatment options. It was also noted that significant adverse effects may impact upon the numbers of patients who complete a course of treatment with anastrozole. **Post meeting note:** NICE has recently published some patient decision aids to support patients with making choices regarding taking medicines to reduce the chance of developing breast cancer https://www.nice.org.uk/guidance/cg164/resources/patient-decision-aids-information-4422436674 **Hypertension in adults: diagnosis and management** NICE guideline [NG136] Published: 28 August 2019 Last updated: 21 November 2023 https://www.nice.org.uk/guidance/ng136 **APC actions:** to be considered via the cardiovascular long-term conditions group. **Transient loss of consciousness ('blackouts') in over 16s** Clinical guideline [CG109] Published: 25 August 2010 Last updated: 21 November 2023 https://www.nice.org.uk/guidance/cg109 **APC actions:** none. See also NG136, above. **The following COVID 19 related information has been produced/updated by NICE:** None published. **The following NICE TAs are the commissioning responsibility of NHSE and are listed for information only:**	

No	Agenda Item	Action
	Birch bark extract for treating epidermolysis bullosa Highly specialised technologies guidance Reference number: HST28 Published: 20 September 2023 https://www.nice.org.uk/guidance/hst28 **APC action:** none – no local use expected (specialist centres only) **Pembrolizumab for previously treated endometrial, biliary, colorectal, gastric or small intestine cancer with high microsatellite instability or mismatch repair deficiency** Technology appraisal guidance [TA914] Published: 20 September 2023 https://www.nice.org.uk/guidance/ta914 **APC action:** link added to Formularies (RED traffic light) **Pegunigalsidase alfa for treating Fabry disease** Technology appraisal guidance [TA915] Published: 04 October 2023 https://www.nice.org.uk/guidance/ta915 **APC action**: none – no local use expected. **Ruxolitinib for treating polycythaemia vera** Technology appraisal guidance [TA921] Published: 18 October 2023 https://www.nice.org.uk/guidance/ta921 **APC action:** link added to Formularies (RED traffic light) **Glofitamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments** Technology appraisal guidance [TA927] Published: 17 October 2023 https://www.nice.org.uk/guidance/ta927 **APC action:** created and link added to Formularies (RED traffic light) **Tabelecleucel for treating post-transplant lymphoproliferative disorder caused by the Epstein-Barr virus (terminated appraisal)** Technology appraisal [TA923] Published: 19 October 2023 https://www.nice.org.uk/guidance/ta923 **APC action:** none – terminated appraisal **Daratumumab with lenalidomide and dexamethasone for untreated multiple myeloma when a stem cell transplant is unsuitable** Technology appraisal guidance [TA917] Published: 25 October 2023 https://www.nice.org.uk/guidance/ta917 **APC action**: links added to formularies (RED traffic light) **Cabozantinib for previously treated advanced differentiated thyroid cancer unsuitable for or refractory to radioactive iodine** Technology appraisal guidance [TA928] Published: 01 November 2023 https://www.nice.org.uk/guidance/ta928 **APC action:** link added to formularies (Cabometyx brand) – not recommended **Lutetium-177 vipivotide tetraxetan for treating PSMA-positive hormone-relapsed metastatic prostate cancer after 2 or more treatments** Technology appraisal guidance [TA930] Published: 15 November 2023 https://www.nice.org.uk/guidance/ta930	

<table>
<tr><th>No</th><th>Agenda Item</th><th>Action</th></tr>
<tr><td></td><td>APC action: none – not recommended

Zanubrutinib for treating chronic lymphocytic leukaemia
Technology appraisal guidance [TA931] Published: 22 November 2023 https://www.nice.org.uk/guidance/ta931
APC action: link added to formularies (RED traffic light)</td><td></td></tr>
<tr><td>7.</td><td>Virtual Recommendations/Documents for discussion/ratification</td><td></td></tr>
<tr><td>7.1</td><td>Guideline for Treatment and Prevention of Migraine / Tension-Type Headache
Following on from the review and discussion of the document at September APC, the Committee considered an updated version of the guideline. This included the following changes:

• Removal of domperidone as an antiemetic choice
• Additional wording adding to specify that the triptans should be taken at the onset of headache.

Decision: The Committee approved the updated guideline.

EQIA Assessment: No impact. The guidance supports but does not change current clinical practice.

BLMK ICB E and D Lead comment: No clinical changes - no additional comments from equality perspective.</td><td></td></tr>
<tr><td>7.2</td><td>Continuous Glucose Monitoring (CGM) update
The Committee considered updated recommendations from the BLMK Diabetes, Insulin Pumps and Technologies Working Group. This related to changes to the existing recommendations to include choices of CGM device in children and young people (CYP) with type 2 diabetes (T2DM).

The cohort of CYP with T2DM treated with insulin is small and it is therefore not expected to affect the overall ability to keep with the allocated budget for CGM. CYP who will be eligible for CGM is in accordance with NICE guidance contained in NG18, and local implementation discussions. The recommendations for device choices are:

<table>
<tr><th>Age</th><th>If follow-app functionality is needed:</th><th>If follow-app functionality is NOT needed:</th></tr>
<tr><td>2-3 years</td><td><u>First line:</u> Dexcom G7</td><td><u>First line:</u> Dexcom G7</td></tr>
<tr><td></td><td><u>Second line:</u> Dexcom G6 (only if pump connectivity required)</td><td><u>Second line:</u> Dexcom G6 (only if pump connectivity required)</td></tr>
<tr><td>4-19 years</td><td><u>First line</u>: FSL3 or FSL2</td><td><u>First line</u>: Dexcom One or FSL3 or FSL2</td></tr>
<tr><td></td><td><u>Second Line</u>: Dexcom G6 (only if pump connectivity required)</td><td><u>Second Line</u>: Dexcom G6 (only if pump connectivity required)</td></tr>
</table>
</td><td></td></tr>
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No	Agenda Item	Action
	Decision: The Committee approved the updates to the BLMK CGM guidance. **EQIA Assessment:** A full EQIA has been completed and approved by ICB Directorate Lead. Rationale is documented in the full assessment. **BLMK ICB E and D Lead comment:** N/A	
7.3	**Ulcerative colitis pathway update** The moderate to severe Ulcerative Colitis treatment pathway has been updated to incorporate Mirikizumab. Mirikizumab is an interleukin inhibitor which has been recently approved by NICE, in TA925, for treating moderately to severely active ulcerative colitis. No significant cost impact is anticipated. This is because the technology is a further treatment option, and the overall cost of treatment will be similar. Additionally, general prescribing notes have been added to supplement the pathway (this includes information regarding the MHRA warnings on JAK inhibitors) and the wording relating to Individual Funding Requests has been updated (as agreed at the September APC meeting). The updated pathway was circulated to specialists for comment, who are in agreement with the proposed changes. **Decision:** The Committee approved the updated pathway. **EQIA Assessment:** Yes, impact anticipated, but in a positive way. An additional treatment option will be available to patients in line with NICE and local guidance. **BLMK ICB E and D Lead comment:** Additional option – no additional comments from equality perspective.	
7.4	**Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis pathway update** NICE has recently published two new technology appraisals for treatments for the management of Ankylosing Spondylitis and/or Non-radiographic Axial Spondyloarthritis (AS / nr axSpA): 1. Bimekizumab for treating axial spondyloarthritis https://www.nice.org.uk/guidance/ta918 TA918 contains recommendations on the use of bimekizumab for treating both active ankylosing spondylitis and active non-radiographic axial spondyloarthritis. 2. Tofacitinib for treating active ankylosing spondylitis https://www.nice.org.uk/guidance/ta920 TA920 contains recommendation on the use of tofacitinib for treating active ankylosing spondylitis only. In both TA918 and TA920, treatment is only recommended if the patient's condition is not controlled well enough with conventional	

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	therapy and tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough. The existing BLMK pathway for AS / nr axSpA has therefore been updated to include bimekizumab and tofacitnib as additional treatment options. No significant cost impact is anticipated. This is because each technology is a further treatment option, and the overall cost of treatment will be similar. In addition, in the "Third and Fourth Line Options" box, wording has been amended from listing individual drug names, to classes of medicines, and the wording relating to Individual Funding Requests has been updated (as agreed at the September APC meeting). The updated pathway was circulated to specialists for comment, who are in agreement with the proposed changes. **Decision:** The Committee approved the updated pathway. **EQIA Assessment:** Positive impact anticipated. The addition of further treatment options to the pathway will benefit patients. **BLMK ICB E and D Lead comment:** Additional options – no additional comments from equality perspective.	
7.5	**Psoriatic arthritis pathway update** The treatment Pathway for Active Psoriatic Arthritis (after inadequate response to DMARDs) has been updated to include Bimekizumab in accordance with NICE TA916 - Bimekizumab for treating active psoriatic arthritis. Changes have also been made to the 'treatment choice considerations' and 'patient/clinical factors to consider' boxes to provide further information about escalated dosing schedules available for specific patient cohorts. In addition, the wording in relation to Individual Funding Requests has been updated as agreed at the September meeting. The updated pathway was circulated to specialists for comment, who are in agreement with the proposed changes. **Decision:** The Committee approved the updated pathway. **EQIA Assessment:** Positive impact anticipated. The addition of further treatment options to the pathway will benefit patients. **BLMK ICB E and D Lead comment:** Additional options – no additional comments from equality perspective.	
8.	**Medicines Safety update** A Primary Care Medicines Safety Update and a Medicines Safety Group Update was presented to the committee. **<u>Primary Care Medicines Safety Update</u>**	

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	This update focussed on the primary care response to the MHRA Drug Safety Updates (September and October 2023). In particular: **Fluoroquinolone antibiotics: suicidal thoughts and behaviour (September 2023)** Healthcare professionals prescribing fluoroquinolone antibiotics (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin) are reminded to be alert to the risk of psychiatric reactions, including depression and psychotic reactions, which may potentially lead to thoughts of suicide or suicide attempts. Healthcare professionals are also reminded to advise patients to be alert to these risks. **Action(s) taken:** Has been discussed in antimicrobial stewardship group, including ways of communicating risks of fluoroquinolone use to patients can be improved. **Statins: very infrequent reports of myasthenia gravis (September 2023)** Globally, there has been a very small number of reports of new-onset or aggravation of pre-existing myasthenia gravis with atorvastatin, pravastatin, lovastatin, fluvastatin, simvastatin, rosuvastatin and pitavastatin (single-ingredient and fixed-dose combination products). Advise patients taking statins to be alert to new symptoms for myasthenia gravis, or worsening symptoms of pre-existing myasthenia gravis, and to seek medical advice if these occur. **Action(s) taken:** Links added to the Formularies and item brought to November MSG for raising awareness/noting. **Valproate: dispense full packs of valproate-containing medicines (October 2023)** Unless there are exceptional circumstances, valproate-containing medicines must always be dispensed in the manufacturer's original full pack. **Action(s) taken**: SystmOne will only allow prescribers to administer full packs therefore this recommendation cannot be deviated from in Primary Care. The group discussed difficulties in mental health settings, as whole pack dispensing may be inappropriate for patients going on short term leave. BHFT also exploring appropriateness of full pack dispensing for those at risk of suicide and overdose. The group explored possible development of a risk form for assessing suitability – ELFT have implemented and plan to share the work with the group. **Isotretinoin (Roaccutane▼): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age (October 2023)** The MHRA has strengthened the safe use of isotretinoin through the introduction of additional oversight of the initiation of isotretinoin in patients under 18 years and through improved assessment and monitoring of mental health and sexual function issues. **Action(s) taken:** Reflections from valproate workstreams will feed into isotretinoin as the principles for avoidance of pregnancy on this medicine are similar. A review of ePACT data has identified a small	

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	amount of prescribing – patients are in the process of being repatriated back to specialist (NB: isotretinoin is RED on both formularies). **ADHD medication shortage NPSA alert (CAS alert, September 2023)** Shortage of methylphenidate prolonged-release capsules and tablets, lisdexamfetamine capsules, and guanfacine prolonged-release tablets – discussed at MSG in November and was reported by partners to be a major challenge. The WhatsApp groups (hosted by Medicines Optimisation team) for sharing of information and stock levels have been extremely helpful. Lisdexamfetamine (Elvanse) continues to be the most challenging as there is no alternative product to switch to easily. See also agenda item 14.1 regarding communications and materials developed / sent out from the ICB and partners. **Potential risk of underdosing with calcium gluconate in severe hyperkalaemia (NPSA alert, June 2023)** **Action(s) taken:** Trusts are in the process of updating guidance. Hyperkalaemia kits are not in use currently at either Trust. **<u>Medicines Safety Group (MSG) Update</u>** The following additional DSU was discussed at the September MSG meeting: **Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions (August 2023)** The MHRA recently received a Coroner's report following a case of a photosensitivity reaction in a patient on methotrexate. This reaction was found to have contributed to their death by secondary infection. Photosensitivity reaction is a known common side effect of methotrexate. The DSU provides advice for healthcare professionals around counselling patients – that their skin may become more sensitive and to take precautions in the sun. **Action(s) taken:** The alert will be circulated to the relevant teams in the Trusts that use methotrexate (Gastroenterology, Rheumatology and Dermatology). This will also be included in the BLMK newsletter for primary care. OptimiseRx have reviewed this MHRA alert and are not planning on producing any messages because these flag as part of the SystmOne workflow (it's already a known side effect which SystmOne deals with). Additional MSG workstreams: **Bounceback forms** The group are in the process of exploring a BLMK wide mechanism for bounceback of inappropriate requests to prescribe medicines in Primary Care. The group is working with the Trusts to establish a reliable and sustainable method of receipt of forms at the Trusts and develop a clear pathway for this.	

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	Sodium Valproate – Pregnancy prevention forms The MSG has formed a task and finish group to develop a pathway to ensure women of childbearing age have a pregnancy prevention form completed. The first subgroup meeting was held on 27th November and engages systemwide partners. Learning from national workstreams is being fed into this project, e.g. the Henrietta Hughes report, which covers a wider range of teratogenic medicines and how risk of exposure in pregnancy can be mitigated. **Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients (NPSA Alert, November 2023)** A subgroup of the MSG has already been formed (see information above) and there was an initial brainstorming of ideas at the meeting on 27th November. **PSIRF workstream** Shared learning is ongoing via MSG as PSIRF embeds into practice. In September, the lead for PSIRF within the ICB (Chris Myers) attended MSG to provide a system update on progress which was well-received by the group. It is anticipated that the main providers to come on board with PSIRF by December 2023 and smaller contractors in the new contract year from April 2024. **SystmOne local Formulary** The Medicines Optimisation team are in the process of building a local Formulary for SystmOne (S1) which is expected to be available to all practices by the end of the year. It is hoped that this will mitigate against prescribing and dosing errors for commonly prescribed medicines, aid Formulary adherence and reduce inter-practice variation in selection of medicines. It was suggested at the meeting that the S1 information in relation to specific dosing information (not just 'take one as directed') for oral contraceptives and HRT needs to be improved and this has been highlighted through prescribing reviews. This will be reviewed and updated as appropriate. **Actimorph (morphine sulphate orodispersible tablets)** This product is on Formulary however uptake is low currently. A presentation was delivered within the MSG meeting to highlight the benefits of prescribing Actimorph over Oramorph and work is ongoing to encourage its use more across the system. **#MedsSafetyWeek (6-12 November)** The Medicines Safety week this year has a focus on who can report to highlight that this is not limited to healthcare professionals. Patients, doctors, nurses, and pharmacists all have a key role to play in the cycle of medicines safety. The MHRA want to explore the different perspectives that come from these groups and how the information they provide can help make medicines safer. Campaign videos have been released and are available in multiple languages.	NC/JWi

No	Agenda Item	Action
	The Committee noted the medicines safety update.	
9.	**Formulary Update**	
9.1	**Formulary Subgroup Recommendations** The following recommendations were made by the Formulary subgroup at the 14 November 2023 meeting: • **Luforbec 100/6 & Luforbec 200/6 (Beclomethasone dipropionate & Formoterol fumarate) pMDI**. Luforbec is a combined ICS/LABA inhaler which is equivalent to Fostair. It is recommended in local and national guidance for the treatment of adult patients: ○ Not adequately controlled on a lower strength ICS inhaler. ○ Not adequately controlled on a lower strength ICS inhaler and have not responded to a trial of leukotriene receptor antagonist. Luforbec 100/6 is also licensed to be used as maintenance and reliever therapy (MART.) MART regimes are currently recommended for adult patients: ○ 1st line as a preferred treatment track in the current GINA guidance. ○ As an option instead of fixed maintenance ICS/LABA + SABA prn in the current BTS guidance. ○ As a 4th line option in the current NICE guidance. The Formulary group have agreed addition to the Formulary (GREEN) as first line choice, with Fostair as second line choice for the above indications. *Cost impact of decision:* large cost-saving. A 40% shift to Luforbec (both strengths) represents a saving of £751,342 per annum. An 80% shift would represent a saving of £1,502,684 per annum. • **Bibecfo 100/6 & Bibecfo 200/6 (Beclomethasone dipropionate & Formoterol fumarate) pMDI.** Bibecfo is another alternative to Luforbec with the same credentials, however it is a very new addition to the market, therefore the group concluded that Luforbec only would be added to the Formulary as Luforbec supplies are more embedded into the market. Bibecfo remains Non-Formulary, as Luforbec (equivalent product) has been added. • **Blood glucose, ketone and lancets review.** NHS England led a national clinical assessment to better understand the products available and how they meet the needs of all people living with diabetes. The NHSE Commissioning recommendations for blood glucose and ketone meters, testing strips and lancets published April 2023 recommends 16 of the 90 currently available meters, giving ICBs the opportunity to review their preferred formulary meters for most type 1 and type 2 patients. The agreed meters are as follows: ○ Group 1 (with ketone testing functionality/dual meter/type 1 diabetes): 4suresmart Duo, Care Sens Dual.	

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	○ Group 2 (for majority of patients with type 2 diabetes): Finetest Lite smart, CareSense S Fit BT, Contour plus Blue and outside of NHSE recommendations Palmdoc 2 (which was chosen for multilungual features to suit the diverse BLMK population). ○ Group 3 (Type 2 diabetics who require additional functionality): Wavesense Jazz, and outside of NHSE recommendations - Palmdoc 2 and GlucoRx Nexus voice (speaking meter for blind or visually impaired patients). *Cost impact of decision*: For most patients changing to one of the cost-effective options with lower acquisition cost (< £6/50strips) and lancets (£3.00/ 100) will support efficiency savings. The extent of the savings realised will be dependent on the percentage of patients switching. • **Adjuvant bisphosphonates in early breast cancer**. Alignment of the Formulary choices of bisphosphonates in the management of early breast cancer for post-menopausal women to improve breast cancer survival. Summary of recommendations agreed: ○ Ibandronic acid is proposed to be removed from the Bedfordshire and Luton Joint Formulary and made 'Non-Formulary' as per the Milton Keynes Joint Formulary but with a note that it can continue to be prescribed for existing patients. ○ Addition of information to both formularies that zoledronic acid is first line (Red) and sodium clodronate second line (SpA) in line for the use of adjuvant bisphosphonates in the treatment of Early and locally advanced breast cancer as outlined in NICE Guideline (101) - Early and locally advanced breast cancer: diagnosis and management, https://www.nice.org.uk/guidance/ng101. ○ Retire JPC bulletin 260 "Addition of adjuvant bisphosphonate therapy to the management of early breast cancer for post-menopausal women to improve breast cancer survival". *Cost impact of decision:* likely low impact of approximately £2,439 (from change of second line choice at Bedford Hospital from ibandronic acid to sodium clondronate). • **Dementia Shared Care Guidance (SCG).** Review and update of the existing Bedfordshire & Luton dementia shared care guideline. Initially proposed to be applicable to Beds/Luton only due to differing arrangements in Milton Keynes. Following further discussions, it was agreed that the SCG would be made suitable as a BLMK document. This will be taken forward and finalised in due course. *Cost impact of decision:* N/A • **Paraldehyde injection and Paraldehyde 50% in olive oil rectal solution for status epilepticus.** Paraldehyde is administered rectally as an enema and is currently on the Beds/Luton Formulary (RED) for use in paediatric patients (unlicensed use). The product is currently not included on the Milton Keynes Formulary. To be added MK Formulary as RED to align with Beds/Luton. Stable existing patients may remain in Primary Care provided GP is happy to continue prescribing. No further patients	

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	to be transferred to Primary Care. Counselling was discussed as a key point for patients to avoid harm from improper administration. *Cost impact of decision:* No impact • **Actinic Keratosis (AK) Formulary choices of topical agents.** The current products on the Formularies are not in alignment with the national Ardens templates which is causing confusion for prescribers and rejection of Optimise Rx messages. This has a negative impact on the trust in the system, as commonly used products are missing from the formulary. The formulary changes are: ○ Addition of diclofenac 3% gel (Solaraze) (GREEN) – This is the most prescribed product in Primary Care for the indication and currently has a Non-Formulary status. (Feedback received that diclofenac is less efficacious however it is also less likely to cause eczematous skin reactions). ○ Addition of imiquimod 3.75% cream (Zyclara) (GREEN) – Recommended in Ardens template for large areas of AK – Currently Non-Formulary. ○ Fluorouracil 5% cream (Efudix) and imiquimod 5% cream (Aldara) – update designation from SpA to GREEN – Commonly prescribed in Primary Care in line with Ardens templates and PCDS state that the majority of cases of AK can be managed in Primary Care. ○ Addition of Actikerall solution (combines 5-FU with salicylic acid) (GREEN) recommended in Ardens for thick solitary lesions – currently Non-Formulary. ○ Klisyri cream (tirbanibulin) – no usage – remain Non-Formulary. *Cost impact of decision:* No impact – prescribing already established. • **Heparin flushes for paediatric community nursing services.** Individuals with intravenous lines (e.g. tunnelled central venous lines or indwelling ports) that are accessed in patients' homes by the community nursing team require heparin flushes to be available in order to maintain the patency of the line. The community nursing team are not currently all non-medical independent prescribers and may therefore require the patient's GP to prescribe as per care plan to ensure continuity of care. Change in formulary status from RED to SpA for heparin sodium flushes (10 units / ml and 100 units / ml) was approved, subject to a clear care plan being in place for the patient and there is clarity around which product is intended to be prescribed. Optimise Rx messages and SystmOne formulary to be updated to further provide clarity. *Cost impact of decision:* Expected cost impact is minimal as patient numbers are low and there is already prescribing occurring in primary care. • **Micronised progesterone (Gepretix) for Hormone Replacement Therapy.** Gepretix is due to become available on the market in January 2024 as a cost-effective bioequivalent alternative to the current formulary choice Utrogestan. Due to the	

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	difficulties sourcing Hormonal Replacement Therapies, it was agreed that Gepretix would be added (GREEN) but Utrogestan would be retained on Formulary. A switch message will be deployed on Optimise Rx for new patients to help support savings**.**
	Cost impact of decision: cost saving – approximately £80k based on 100% switch.
	• **Attention Deficit Hyperactivity Disorder Shared Care Guidance (Adults).** Shared care agreement between Milton Keynes primary care and Psychiatry-UK (commissioned provider of NHS ADHD service for adults in MK). Intended primarily for MK locality only but may also apply to NHS adult patients from Beds/Luton who have exercised their Right To Choose (RTC) to access ADHD service provided by Psychiatry-UK under the NHS. As part of the proposal, guanfacine was also agreed to be moved to AMBER SCG traffic light (previously RED on the MK formulary) and methylphenidate / lisdexamfetamine / dexamfetamine / atomoxetine: SpIS formulary status changes to AMBER SCG were approved.
	Cost impact of decision: n/a
	• **Melatonin (Ceyesto) oral solution for insomnia in children and adolescents aged 6-17 years with attention deficit hyperactivity disorder (ADHD), where sleep hygiene measures have been insufficient.** Ceyesto 1mg/1ml oral solution (a new cost-effective licensed preparation of Melatonin) has been launched and is due to be available in wholesalers November 23. Current Beds/Luton & MK formularies have KidMel 1mg/mL oral liquid (unlicensed special for children under 5 years due to its lower Propylene Glycol (PG) content) and Colonis preparation 1mg/mL oral solution (licensed product being used off label for children over 5 years as has higher PG content). The proposal to remove Kidmel and Colonis liquids and replace with Ceyesto liquid was approved. The indications for Ceyesto will include both the licensed indication for ADHD and off-label indications in children where clinically appropriate.
	Cost impact of decision: Ceyesto is a 1/5th of the cost of other 1mg/ml oral solutions – potential to save £400K if 100% switch across BLMK.
	• **Ximluci (ranibizumab cost-effective biosimilar) and Yuflyma (cost-effective adalimumab biosimilar)** (noting). Two new brands in use at the Trusts:
	  ○ Ximluci for use in Beds/Luton and Milton Keynes
	  ○ Yuflyma for use in Milton Keynes.
	It was agreed that going forward applications were not required for biosimilar brand switches (but the commissioning team will still need to be made aware of any changes in order to allow update of BlueTeq forms). Applications will still be required for new biosimilar medicines.
	Cost impact of decision: Cost-saving for secondary care.
	• **Levonorgestrel 20 micrograms/24 hours Intrauterine Delivery System (Benilexa® One Handed Intrauterine Device).** Benilexa is a cost-effective alternative to Mirena. It is licensed for contraception and Heavy Menstrual Bleeding (but not endometrial	

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	protection) and is endorsed by the Faculty of Reproductive and Sexual Health (FRSH). Similar insertion process to Mirena, however one possible negative identified is that the introducer is wider which is less comfortable for patients during insertion. The manufacturer has indicated they may be able to train some staff and the applicant has indicated she will include Benilexa in any training for new GPs on an ad hoc basis. Benilexa is a long acting reversible contraceptive device – other devices in this category are cross-charged back to public health via the councils therefore their agreement has been sought for this. The addition of Benilexa to the formulary (GREEN) was approved, pending authorisation from Luton council as the final outstanding stakeholder. *Cost impact of decision:* Small cost-saving – small uptake expected. • **Torasemide for use during bumetanide shortage.** Torasemide has been approved temporarily (GREEN) on both Formularies during the period of bumetanide shortage. It is anticipated that the majority of patients will be managed with furosemide, however in consultation with cardiology there is a need to support people with heart failure and oedema that are unable to tolerate or are resistant to furosemide with an alternative diuretic. It was agreed to add torasemide for these patients only for use where bumetanide cannot be sourced for a patient in any other strength or form. All efforts to maintain patients on regular bumetanide must be exhausted prior to switching. *Cost impact of decision:* estimated £10,000 for 4 months. In addition, the Committee noted the Formularies minor amendment log. **Decision:** The committee ratified the recommendations of the Formulary Subgroup.	
9.2	**Wound Management Formulary Steering Subgroup Recommendations** A report from the wound management subgroup meeting held on 22 November 2023 was presented to the Committee: **Formulary Alignment and Development:** Jobst UlcerCare kit (approved at the last APC meeting) has been added to both the Bedfordshire & Luton and Milton Keynes Wound Management Formularies. Members of the Group are meeting with the provider of the MK ordering system to see whether a one-stop approach can be adopted. **Financial:** Spend in MK is being investigated with high-spending practices to be approached to ensure purchasing is effective and efficient. A stock take project is planned for 2024. Further sites in Bedfordshire have been set up as ordering points for wound care products which should help reduce FP10 spend and promote cost savings.	

No	Agenda Item	Action
	Online formulary: The phrase "Restricted use – preferably on the advice of a TVN: ensure relevant pathways are consulted" has replaced "TVN Use Only" to maintain use of high value dressings only when clinically appropriate. The draft version of the Milton Keynes Practice Nurses formulary is still being reviewed. Technical issues with presentation of the online formulary have been taken up with the website providers. **Waste Reduction in Wound care** This is an issue the Group are aware of and keen to implement. At the November meeting the Group shared information around recyclable bowls and liners that are suitable to use in wound care. This consideration will be incorporated into formulary reviews going forward. **Decision:** The Committee ratified the recommendations of the Wound Management Steering group	
10.	**Patient Group Direction Subgroup Recommendations** 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: The following PGDs were presented for approval with clinical changes: • **Amoxicillin and Doxycycline** for acute bronchitis: Aligned eligibility criteria to BLMK guidance: Is systemically very unwell at face to face examination or at higher risk of complications including: 1. People with a pre-existing co-morbidity 2. >80years and 1 of the following or >65 years with 2 of the following: ➢ hospitalisation in the past year ➢ taking oral steroids ➢ type 1 or 2 diabetic ➢ congestive heart failure Also added Counsel on self-care and provide safety netting. • **Fusidic acid 2% cream** for non-bullous impetigo – added to eligibility criteria: if hydrogen peroxide 1% cream is unsuitable or ineffective. • **Hydrocortisone cream 1%** for mild to moderate inflammatory skin disorders – added: If skin condition worsens within 2 weeks of stopping a topical corticosteroid, treatment should not be started again without consulting a healthcare professional. • **Omeprazole 20mg capsules** (gastroprotection – for use in conjunction with the Naproxen 250mg tablets PGD – see below) – added warning about driving. The following PGDs were presented for approval with no clinical changes:	

No	Agenda Item	Action
	• **Lidocaine injection 1%** - local anaesthesia for wound closure, cleaning or examination • **Miconazole cream 2%** for infected nappy rash and skin ringworm • **Naproxen tablets 250mg** for acute MSK disorders • **Otomize ear spray** for Otitis Externa • **Permethrin 5% cream** for the treatment of scabies • **Senna** for the treatment of constipation • **Tetracaine 0.5%** - local anaesthesia for eye examinations and treatment • **Metoclopramide 10mg injection** for more severe nausea & vomiting with known cause. **Decision:** The Committee ratified the PGDs as recommended by the PGD subgroup.	
11.	**Antimicrobial Resistance Update** The antimicrobial system wide group met two weeks ago, and regional and local prescribing data were reviewed. The primary care data was presented at the APC meeting. • Primary care data indicates that total antibiotic prescribing remains raised. It was noted that the data is based on a rolling 12 month period, so it is expected to remain raised until >12 months have passed since last year's group A strep outbreak. It is therefore not expected to come down until approximately April 2024. • S1 formulary (see also agenda item 8.0) – plan to build in an antimicrobial formulary, including information on indications and appropriate course length, into the S1 formulary. The Committee noted the antimicrobial stewardship update.	
All other papers (from this point in the agenda) are for noting/information by the Committee		
12.	**East of England Priorities Advisory Committee (EoEPAC) – items for noting/approval**	
12.1	EoEPAC Meeting Notes – July 2023 The committee noted the minutes for information.	
13.	**Bedfordshire, Luton and Milton Keynes Local Prescribing Committee Minutes.** The Committee noted the following minutes for information.	
13.1	Minutes of the Bedfordshire Hospitals Foundation Trust Drug and Therapeutics Committee (DTC) – September 2023	
13.2	Minutes of the Milton Keynes Hospital Prescribing & Medicines Governance Committee (PMGC) – October 2023	
13.3	Minutes of the BLMK Formulary Subgroup – September 2023	

No	Agenda Item	Action
13.4	Minutes of the BLMK Wound Management Formulary Steering Group – September 2023	
13.5	Minutes of the BLMK Medicines Safety Group – August and September 2023	
13.6	Minutes of the ELFT Medicines Management Committee – September 2023	
13.7	Minutes of the Cambridgeshire Community Services Medication Safety and Governance Group – July & September 2023	
13.8	Minutes of the CNWL Trustwide Medicines Optimisation Group (MOG) – *none approved since last APC meeting*	
13.9	Minutes of Circle/MSK Medicines Management Committee – September 2023	
14.	**Papers for information / ratification**	

14.1	**ADHD medicines shortages communications to primary care**
	In response to the ADHD NPSA alert, published September 2023, urgent actions needed to be undertaken in order to comply with the timescales for action in the alert. The specialist teams, working together with the ICB Medicines Optimisation team, produced supporting documents which were approved by APC chair's action prior to circulation in primary care. The details of the chair's action have been recorded in the chair's action log.
	
	The following communications were approved:
	
	• East London Foundation Trust
	  ○ ADHD BLMK memo
	  ○ ADHD information for schools
	  ○ ADHD patient information leaflet
	  ○ ADHD easy read patient information leaflet
	• Central and North West London NHS Foundation Trust
	  ○ ADHD supply shortage memo
	
	The Committee noted and ratified the documents.	

14.2	**Pharmacy First** Information was shared with the Committee regarding Pharmacy First – a new advanced service for community pharmacies in England which is scheduled to launch on 31st January 2024, subject to the successful deployment of IT systems. The service is designed to reduce some of the pressures on GP practices and will replace the existing Community Pharmacist Consultation Service (CPCS). It is expected to improve patient access to NHS treatment for minor illnesses and increase utilisation of community pharmacies. The Pharmacy First service will initially cover the following seven conditions: • Sinusitis • Sore throat • Acute otitis media (ear infection) • Infected insect bite • Impetigo (skin infection)	

No	Agenda Item	Action
	• Shingles • Uncomplicated urinary tract infections in women Pharmacists will be able to provide advice and, where appropriate, NHS-funded treatment for the above conditions using Patient Group Directions (PGDs). There are 23 PGDs currently in development and available in draft form in preparation for the service going live. Patients may self refer to this service, but they may also be referred to the service by their GP or another healthcare professional. In addition to Pharmacy First, two new services will be launched in December 2023: • **Expanded blood pressure check service:** This service will provide more frequent blood pressure checks for patients at risk of high blood pressure, with a target of 2.5 million checks per year by Spring 2025. • **Contraception service:** This service will enable pharmacists to initiate oral contraception for women, in addition to the existing service of providing ongoing supplies of oral contraception. The Committee discussed the following points: • The need for considered and appropriate use of antibiotics with the Pharmacy First service. • Consideration needed with regards to visibility of care, and associated treatment, provided in secondary care – e.g. the patient may have had a recent admission to hospital and received antibiotics as part of their care. Concerns regarding lack of visibility for community pharmacists of secondary care prescribing, and prescribing by dentists, to be fed back. • The digital enablement for the service is still being developed and the service will not be launched until the IT solutions are in place. • Even with the IT solutions in place there may not be full visibility to patient records as some patients may not have consented for their records to be shared. • Concerns were raised around the capacity of community pharmacies to offer the service and it was clarified that, as it is an advanced service, pharmacies need to opt in to take part. Pharmacies will also need to meet certain criteria in order to be able to offer the service. • Contraception service – concerns were raised regarding the knowledge base of participants of the scheme and the importance of keeping up to date with current guidance. To be picked up outside of the meeting as part of the discussions around the development of local contraception guidance. The Committee noted the information on the Pharmacy First, extended blood pressure checking and contraception services.	FB JWi/ SMcG
15.	**Any other business** BLMK APC deputy Chair – it was noted that there is currently no deputy chair to the Committee and a proposal was put forward that	

No	Agenda Item	Action
	this role could be fulfilled by Dr Lindsey Mackenzie, GP in Bedford and deputy to Dr Jenny Wilson (as Bedford place based GP representative on the APC). Dr Mackenzie also currently chairs the BLMK Primary Care Prescribing Committee. The Committee agreed the proposal and noted that Dr Mackenzie will attend meetings in her new capacity as deputy chair.	
16.	**Future Dates for BLMK APC 2023 / 2024 Meetings (all to be held from 12:30-15:00 via Microsoft Teams):** Wednesday 28th February 2024 Wednesday 1st May 2024 Wednesday 3rd July 2024 Wednesday 25th September 2024 Wednesday 4th December 2024	

Approval of minutes:

Chair: Dr Muhammad Nisar

Signed: 

Date: 29 Feb 2024

Appendix 1 – Approved 14 November 2023 Formulary Subgroup Minutes:

FSG Minutes Final November 2023.pdf