BEDFORDSHIRE, LUTON AND MILTON KEYNES AREA PRESCRIBING COMMITTEE

DRAFT Meeting Notes

Date: 29 June 2022
Time: 12.30- 3.00pm
Venue: Microsoft Teams

Attendees:

Name	Initial	Role
Alison Borrett	AB	Chair (Non-Executive Director BLMK CCG)
Pritesh Bodalia (from 12.36-13.37 and 13.48-14.15)	PB	Bedfordshire Hospitals Trust Pharmacy Representative (Chief Pharmacist, Bedfordshire Hospitals Trust)
Helen Chadwick	HC	Milton Keynes Hospital Pharmacy Representative (Chief Pharmacist, Milton Keynes Hospital)
Quynh Nguyen	QN	ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton)
Yolanda Abunga	YA	CCS Pharmacy Representative (Community Services Pharmacist, Beds and Luton)
Reginald Akaruese	RAk	CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes)
Dr Muhammad Nisar (until 13.40)	MN	Medical Representative, Bedfordshire Hospitals NHS Trust
Dr Marian Chan (from 12.49)	MC	Medical Representative, Bedfordshire Hospitals NHS Trust
Dr Dush Mital (until 13.57)	DM	Medical Representative, Milton Keynes Hospital
Fiona Garnett	FG	Associate Director and Head of Medicines Optimisation BLMK CCG

Naomi Currie	NC	Place Based Lead Pharmacist - Bedford
Mojisola Adebajo	MA	Place Based Lead Pharmacist – Milton Keynes
Matt Davies	MD	Place Based Lead Pharmacist – Central Bedfordshire
Dr Jenny Wilson	JW	Place Based Lead GP - Bedford
Dr Richard Simpson (absent between 13.00-13.22)	RS	Place Based Lead GP – Milton Keynes (deputy to Dr Fagan)
Dr Kate Randall	KR	Place Based Lead GP – Central Bedfordshire
Dr Mitan Sarkar	MS	Place Based Lead GP - Luton
Carole Jellicoe	CJ	Nurse Representative (Independent Prescriber)
Dr Samantha Chepkin	SC	Consultant in Public Health
Cheryl Green	CG	Patient Representative
Anne Graeff	AG	Commissioning Lead Pharmacist, BLMK CCG (Professional Secretary)
Jacqueline Clayton	JC	Chair of Wound Care Group
Dr John Fsadni	JF	Chair of Formulary Subgroup

In attendance:		
Dr Joy Mutitika	JM	Medical Representative, Keech Hospice
Lesley Bates (until 14.04)	LB	Representative, St John's Hospice
Candy Chow	CC	Principal Pharmacist, Milton Keynes Hospital
Dona Wingfield (until 13.57)	DW	Commissioning Lead Pharmacist, BLMK CCG
Raye Summers	RS	PA to MOT, BLMK CCG (admin support)
Sandra McGroarty	SMcG	Commissioning Pharmacist, BLMK CCG
Taiya Large	TL	Formulary and Medicines Safety Pharmacist BLMK CCG
Rafal Ali (absent between 13.03-14.28)	RA	Commissioning Pharmacist, BLMK CCG
Nikki Woodall	NW	Lead Medicines Optimisation Technician , BLMK CCG
Clare Morlidge (for agenda item 5.6)	CM	Pharmacist Advanced - Lead Renal Medicine, East and North Hertfordshire NHS Trust

Apologies:		
Mary Evans	ME	Interim ICS Chief Pharmacist, BLMK
Suraiya Chandratillake	SC	ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton)
Dr Nigel Fagan	NF	Place Based Lead GP – Milton Keynes
Dr Andrew Cooney	AC	Medical Representative, Milton Keynes Hospital
Maire Stapleton	MS	Formulary Manager, Buckinghamshire Integrated Care Partnership
Zainab Alani	ZA	Chair of Medicines Safety Group

No	Agenda Item	Action
1.	**Welcome, Introductions and Apologies** The Chair welcomed everyone to the meeting. Apologies were received and noted as above. The Chair thanked Mary Evans for her service to the Committee, and for her long service to the NHS within BLMK. The meeting was confirmed as quorate.	
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. There were no other declarations of interest relating to the agenda.	
3.	**Minutes of 4th May 2022 APC meeting** The minutes were approved.	
4.	**Matters Arising**	
4.1	**Feedback on miscellaneous actions not included on the agenda from APC meetings**	
4.1.1	**Type 1 diabetes in adults: diagnosis and management, NICE guideline [NG17] Published: 26 August 2015 Last updated: 21 July 2021. https://www.nice.org.uk/guidance/ng17** EoEPAC Secretary to review PAC Guidance. Update 20/04/2022 - PAC have reviewed current relevant bulletins in the light of this guidance and the revised bulletins will be brought to the Committee when published. This is therefore an ongoing action.	AG
4.1.2	**Dapagliflozin and Type 1 Diabetes – licence change** - CCG Lead Diabetes Pharmacist to produce information/flow chart to guide GPs on which patients should or should not receive the combination. **Update 01/06/22** - Following the May APC meeting, the implementation resource has been finalised and shared with practices. It was proposed and agreed that this action could be closed.	Close
4.1.3	**Infliximab s/c – approved December 2021 – standard doses only**. HCD pathways to be updated to include infliximab s/c – The	Close

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	APC agreed that these could be updated and approved by Chair's action. **Update 14/06/22** – the relevant pathways have been updated and approved via Chair's action. It was proposed and agreed that this action could be closed.	
4.1.4	**BLMK Shared Care Guideline Template (revised)** – at the December meeting, it was noted that there were still communication issues relating to blood test results, between primary and secondary care within BLMK and also for patients being seen outside of area. There were also issues in secondary care where e.g., blood tests undertaken at Bedford Hospital could not be accessed at the L & D Hospital and vice versa. It was agreed that while this sat outside of the ability of the committee to resolve (IT and commissioning of services), it was still a medicines safety issue. DW therefore agreed to raise with planned care at her next scheduled meeting and to report back. **Update 15/06/22** - This is an ongoing action	DW
4.1.5	**Strategies to support reduced inhaler carbon emissions** EQIA statement to be updated, as agreed at the December APC meeting. **Update 15/06/22** – This is an ongoing action	DW
4.1.6	**Lipid pathway implementation** At the March APC meeting, it was agreed that the Committee would be kept informed of the progress of implementation of the lipid pathway/of the lipid clinic. **Update 06/06/22** - The clinic will be taking referrals from June. Information will be circulated to practices and shared with the committee. This is an ongoing action.	MD
4.1.7	**Adult ADHD shared care guideline** Updates to be undertaken as identified prior to, and discussed at, the March APC meeting. **Update 15/06/22** – the update of the SCG is underway. This is an ongoing action.	RJa/ELFT
4.1.8	**Localised Severe Psoriasis** Local review to be undertaken of PAC policy to include: number of lines of therapy available and choice of therapy (following comments received by local clinicians). **Update 01/06/22** - PAC is reviewing the evidence for the therapies in response to the feedback from BLMK - the outcome of this is awaited and clinicians have been informed. This is therefore an ongoing action.	AG
4.1.9	**Blood glucose monitoring / SGLT2i for CVD/HF** Outcome of the ICS Transitional Interim Leadership Team's (TILT) consideration of the affordability of implementation of the diabetes NICE guidelines for blood glucose monitoring and SGLT2 inhibitors (SGLT2i) for cardiovascular disease/heart failure (CVD/HF) to be fed back at June APC meeting.	Close

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	Guidance on the Management of Type 2 Diabetes in Adults with CVD and HF with SGLT2i: TILT was asked to make a decision around the affordability and the potential next steps for implementation of the NICE guidance. The TILT agreed to support the APC recommendation of adopting the NICE guidance but focussing on patients where the recommendation is to *offer* therapy, i.e. people with established CVD or heart failure, and focussing on patients with existing drug therapy where there is likely to be the greatest benefit to patients. The TILT requested that the Medicines Optimisation team works with clinicians to ensure patients where NICE recommend the SGLT2i as an 'offer' are prioritised for review. **Intermittent and Continuous Glucose Monitoring in Diabetes** TILT discussed the NICE recommendations on blood glucose monitoring and agreed to support the APC recommendation of adopting the NICE guidelines. An in-year budget of £700,000 was agreed to allow for an increase from 33% to 50% of all type one diabetic patients being given the newer technology (lower acquisition cost products) and those patients with type two diabetes who will benefit the most and where it is likely to be cost effective; for example, patients with dementia requiring multiple health care professional visits daily to monitor blood glucose. This will align BLMK ICS to the England average. It was proposed and agreed that this action could be closed.	
4.1.10	**SGLT2 inhibitors for chronic kidney disease** Criteria for referral to nephrology for patients with CKD (without T2DM) to be confirmed. **Update 01/06/22** - referral pathway awaited from renal specialists. This is therefore an ongoing action.	MA
4.1.11	**SGLT2 inhibitors for chronic kidney disease (+/- type 2 diabetes)** Clear information to be provided on both joint Formularies, and via Scriptswitch/Optimise messages, to support prescribers making treatment choices. **Update 09/06/22** - Both joint Formularies and Scriptswitch/Optimise messages have been updated accordingly. It was proposed and agreed that this action could be closed.	Close
4.1.12	**Blood glucose monitoring** Formation of working group to discuss choice of technologies and practicalities of implementation. Output to be brought to future APC meeting. **Update 01/06/22** - work has begun to enable implementation of the guidance. A paper will be brought to the committee for consideration at the September APC meeting. This is therefore an ongoing action.	AJ/RJ
4.1.13	**Hydroxychloroquine MHRA drug safety alert** Scriptswitch / optimise messages to be deployed to highlight the MHRA DSU to prescribers.	Close

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	Update 18/05/22 - unable to activate additional messages to highlight the DSU as the information is already listed in the warnings within SystmOne. It was proposed and agreed that this action could be closed.	
4.1.14	**Otitis media (acute): antimicrobial prescribing (NG91)** Application to be taken to Formulary subgroup (FSG) for eardrops containing an anaesthetic and analgesic (Otigo). **Update 07/06/22** - Application submitted to June FSG for consideration (declined due to concerns about the evidence for the available product and POM status – see agenda item 8.1 for further information). It was proposed and agreed that this action could be closed.	Close
4.1.15	**Medicines Safety Group (MSG)** MSG to consider removal of brand names in the circulation of the MHRA drug safety updates, and the wider use of pregabalin (outside of the epilepsy indication) when considering the risks of use in pregnancy. **Update 15/06/22** - This is an ongoing action	DW/ZA/LL
4.1.16	**Wound care – addition of Cavilon Advanced** Cavilon advanced skin protectant to be added to the MK formulary as Amber 1 (to be prescribed by TVN or GP on recommendation of TVN only). **Updated 07/06/22** - Cavilon advanced has been added to the MK Formulary. It was proposed and agreed that this action could be closed.	Close
4.1.17	**Blood test monitoring under shared care** Frequency of blood test monitoring under shared care (reversion to pre-COVID monitoring frequencies) - MC to confirm with specialist team regarding monitoring frequency for patients being managed purely by the specialist team e.g. subcutaneous methotrexate. **Update 07/06/22** - discussed with specialist team who will continue with 3 monthly monitoring as per the DMARD SCG. Once the new BSR guidelines are available, this can be reviewed and the SCG updated accordingly. Added to workplan for review following publication of BSR guidelines. It was proposed and agreed that this action could be closed.	Close
5.	**Items for consideration at meeting**	
5.1	**Place in therapy of Drugs for the Treatment of Type 2 Diabetes** One of the MKPAG legacy actions was for the BLMK to review the place in therapy of Drugs for the Treatment of Type 2 Diabetes and it was agreed that this action would be undertaken after NICE had issued its updated NICE Guideline (NG28 - Type 2 diabetes in adults: management). As part of the NG28 update, NICE has produced a number of resources for prescribers including three visual summaries. It was proposed that BLMK APC adopts and promotes these visual summaries for prescribers with the caveat that prescribers should	

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	read the information alongside the Milton Keynes Joint Formulary and the Bedfordshire and Luton Joint Formulary, selecting local Formulary choices from the NICE list of suitable medicines. NB – while the committee were asked to support the general resources produced by NICE, there are local restrictions on implementation due to affordability within the ICS. NG28 recommends the following for SGLT2 inhibitors: Based on the cardiovascular risk assessment for the person with type 2 diabetes: • If they have chronic heart failure or established atherosclerotic cardiovascular disease, *offer* an SGLT2 inhibitor with proven cardiovascular benefit in addition to metformin. • If they are at high risk of developing cardiovascular disease, *consider* an SGLT2 inhibitor with proven cardiovascular benefit in addition to metformin. The ICS has approved funding for patients with established cardiovascular disease or heart failure where NICE recommend that a SGLT2i should be *offered* as a management option. Reviews should prioritise this patient group, where the greatest benefit is anticipated. At the current time funding has not been approved for patients at high risk of developing CVD (NICE '*consider*' recommendation). The Medicines Optimisation team have also included SGLT2i in the Prescribing incentive Scheme (PIS) 2022/23 for practices to support this. The committee discussed the proposal and agreed that the NICE resources should be promoted within the ICS (noting the caveats as outlined above). A query was raised regarding how prescribers would be reminded of which patients should be prescribed SGLT2i at this time and it was confirmed that information has been added to the Formularies to support this, and that additional information has been distributed to practices as part of the PIS work. **EQIA Assessment:** not assessed **BLMK CCG E and D Lead comment: N/A**	
5.2	**Interim commissioning statement – high cost drugs for young people under the care of adult services** Since the formation of NHS England and Clinical Commissioning Groups in 2013 the majority of commissioning of services for children, and associated medicines, has been the commissioning responsibility of NHS England. However, this commissioning responsibility is restricted to patients who are under the care of specialist paediatric centres (this may be shared care with secondary care). The CCG has been monitoring this activity and have noted receiving an increase in the frequency of high cost drug (HCD) funding requests from the adult clinical teams at secondary care trusts for patients aged <18 years who are under their care i.e. on	

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	the adult pathway. To date these requests have primarily been for gastroenterology indications. NHS England has the following information in their HCD list regarding commissioning responsibility and commissioning criteria for HCDs, last updated 5th May 2022: • Where the funded indication is for paediatric use the CCG/ICS will become the responsible commissioner when the patient is transferred to the adult service. • Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy and a Blueteq form is available. This includes drugs normally commissioned by CCGs/ICS in adults (e.g. adalimumab, etanercept, infliximab, etc). Please note that medicines funded under the NHS England Medicines for Children Policy may have additional criteria with respect to access. To standardise process and respond to the needs within the local ICS for funding of HCDs for clinical indications which would generally be funded by NHS England for children and young people (CYP), and then transfer to CCG routine commissioning for adults, it was proposed that an interim commissioning statement is adopted. The criteria allow for the routine commissioning of treatments for patients who are 16 or 17 years old and under the care of adult services, and who meet the criteria for commissioning for children treated within specialist paediatric services. The conditions above will not apply if: • The medicine is routinely commissioned by the CCG/ICB for the medication and condition being requested i.e. there is NICE technology appraisal guidance or a local policy available which applies to children and young people <18 years of age and the CCG/ICB is the responsible commissioner. • The medicine is not routinely commissioned by the CCG/ICB for the medication and clinical condition being requested. • The request is received from a Trust in another area and the host commissioner has a different policy in place (informal or formal). If the conditions are not met, submission of an individual funding request (IFR) will be required. The estimated cost impact is minimal as the CCG is already funding requests on an ad-hoc basis. The committee discussed the proposed interim commissioning statement, and it was clarified that funding for adults would be unchanged, as per NICE and/or local policy, and that for children aged 16/17 the principles proposed in the commissioning statement	

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	will apply. This will often be in line with NICE TAs for adult patients but will depend upon the available evidence for clinical efficacy and safety in under 18s. Blueteq forms will be made available to allow clinical teams to request funding for this patient cohort. This will simplify the process, making it more streamlined and user friendly for Trusts and the CCG/ICB. The committee approved the Interim Commissioning Statement. **EQIA Assessment:** Yes – this will have a positive effect on children under the care of adult services, allowing them to access treatments without undue administration and delay. **BLMK CCG E and D Lead comment:** Interim Commissioning statement does not require Equality Impact Assessment because: Service provision is not new but there is a new policy that is more likely to improve service. Previously, not all CCGs had a specific commissioning policy to cover this service. The new policy by NHS England will uniform the service across providers and reduce the chance of inequality and discrimination so it is likely to have a positive impact. Also, this policy would have been Equality impact assessed by NHS England and there is no need for further equality impact at CCG level.	
5.3	**Ulcerative Colitis Pathway update** Bedfordshire and Luton CCGs have had a biologic treatment pathway for Moderate to Severe Ulcerative Colitis in place for some years and when last updated (September 2020), there had been an attempt to produce a BLMK wide pathway which was unsuccessful due to differences in practice and commissioning within the different areas. The purpose of the update was fourfold: 1. To add Filgotinib to the pathway in accordance with the newly published NICE TA (published 1st June 2022). 2. The amendment of the pathway to place JAK inhibitors (tofacitinib and filgotinib) and vedolizumab in the 'First line treatment options' box in line with NICE TAs. 3. Extend the pathway for use across BLMK. 4. Extend the number of sequential treatment options Information was requested from both local Trusts to help inform the pathway review, and additional information was gathered from a review of Blueteq applications over the last 2 years (excluding requests for Acute Exacerbation treatment). All medicines included in the pathway are subject NICE Technology Appraisal Guidance which confirms clinical and cost-effectiveness and sets out criteria for use of these agents as outlined in the current and proposed pathway. A literature search was undertaken by Bedfordshire Hospitals Trust library service to examine the clinical evidence for sequential use of treatments. Excerpts from abstracts and papers show that there is some very limited evidence that biologics/small molecule drugs can be effective treatments at third	

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	line and beyond, although they may be less effective for patients with prior exposure to biologics, and their efficacy may depend on whether previous biologic treatment lines were halted due to adverse reactions or treatment failure. The main evidence centres on newer agents (e.g. Tofacitinib) used after 1 or 2 Tumour Necrosis Factor Inhibitor (TNFi) failures. Many of the studies are available as abstracts only which made them difficult to evaluate in full. While there are a variety of studies, many of those most relevant are retrospective observational studies of real world data or systematic reviews with network analysis of these studies. The recently published NICE technology appraisal guidance for Filgotinib for the treatment of Ulcerative Colitis does recommend third line use while acknowledging that evidence of clinical evidence is lacking for this treatment option. Cost and cost-effectiveness: As per the relevant NICE TAs, all recommended treatment options included in the pathway have been assessed by NICE and are considered to be cost-effective in this patient population. The existing local pathway also states the following: 'If more than 1 treatment is suitable, the most appropriate, least expensive should be chosen (taking into account administration costs, dosage and price per dose). Biosimilars are cost-effective treatment options.' Additional cost impact is dependent on sequencing of drugs within the pathway and what is used as comparator which could include medicines or surgery. Going forward, filgotinib is likely to be used further up the pathway as it is an oral treatment and very cost-effective, therefore Tofacitinib (same class of drug – JAK inhibitor (JAKi)) is less likely to be used at line 4. A literature search was undertaken by Bedfordshire Hospitals Trust library service on the cost-effectiveness. Finding evidence of cost-effectiveness is difficult, especially considering the different funding and procurement processes across different healthcare systems. A few studies looked at cost-effectiveness for biologics or JAKi for patients who had prior exposure to biologics but none seem to have specifically examined this at third line and beyond. Evidence to support the extension of the pathway to 3rd/4th line drug treatment options with respect to cost-effectiveness is limited. From a review of Blueteq data from local Trusts, it appears that 3rd line treatments are in use and the latest NICE Guidance supports the use of filgotinib at this position. Many other areas have already approved 3rd line treatment and beyond. Surgery appears to be a more cost-effective option but it is not without risks and additional lines of therapy could delay the need for surgery and would be needed in patients who are unsuitable for surgery. The additional cost pressure for 4th line use is subject to multiple factors and therefore very difficult to estimate. It is likely to be in the region of £90,000 to £135,000 per year but may be less depending on sequencing of treatments with the patient pathway.	

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	Comments were received from MKUH in advance of the meeting, but also from clinicians at Bedfordshire Hospitals Foundation Trust (BHFT) within the 24 hours leading up to the APC meeting. Aside from the comment about dose escalation [see below], the Clinicians at MKUH and the Bedford site of Bedfordshire Hospitals Trust were supportive of the pathway. One issue raised includes dose escalation of different biologics. Clinical and cost effectiveness, and licensing, of dose escalation of the different medicines will be examined and brought back to a future meeting for consideration. It was proposed that the committee accept the presented pathway as an interim guideline, that the pathway would then be discussed with the Gastroenterology team at Bedfordshire Hospitals, and then approved by Chair's action (assuming no significant changes were required following the meeting). It will be brought back to the committee for further discussion if significant changes are requested/required. A query was raised regarding whether the same approach could be adopted for the cost pressure as has been assumed for Rheumatology pathways in the past e.g. patients are likely to stay on the previous line of therapy and therefore there may be cost neutrality when extending to fourth line. It was confirmed that there is likely to be some offsetting, but it is difficult to quantify. MN agreed to contact gastroenterology colleagues (on behalf of the Committee) at Bedfordshire Hospital Trusts around patient numbers at different parts of the pathway. The committee agreed the proposed approach, with interim approval of the pathway pending discussion with Gastroenterology specialists at BHFT. **EQIA Assessment:** Yes – but in a positive way. The extension of treatment options (as per new NICE TA for filgotinib) and lines of therapy within the commissioned pathway from 2 to 4 will benefit patients. Patients who reach the end of the pathway can be considered for additional treatment options via the CCG Individual Funding Route. **BLMK CCG E and D Lead comment:** This is not a new policy. The pathway is being extended that was restricted to number of sequential lines of therapy (2 Lines), to be offering 4 lines of therapy. This is likely to give individuals more and better choice for health outcome and likely to have a positive impact. There is no need to carry out full equality impact assessment due to this is an existing policy that is supporting the extension of the pathway with clinical evidence and by NICE Guidance.	MN JC/AG
5.4	**Bempedoic acid formulary amendment** In line with its NICE TA694 Bempedoic acid with ezetimibe was approved by Luton and Bedfordshire Joint Prescribing Committee and Milton Keyes Prescribing & Medicines Governance Committee as an option for treating primary hypercholesterolaemia	

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	(heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults in line with the recommendations within the TA. The original decision was to recommend that bempedoic acid should be initiated in secondary care with GPs to continue Prescribing (AMBER / AMBER 1 on the Bedfordshire & Luton / Milton Keynes joint Formularies respectively). Since this decision the Accelerated Access Collaborative (AAC) have updated their National Guidance for Lipid Management for Primary and Secondary Prevention of CVD (which is NICE endorsed). Additionally, it has been recognised locally that the majority of patients who would qualify for bempedoic acid would not meet the criteria to be seen within secondary care lipid clinics or the community lipid clinic. Consequently, most patients who would qualify for bempedoic acid treatment would be managed within primary care. It was therefore proposed that bempedoic acid is moved to green on the formulary and prescribed as per the ACC Lipid management pathway. This change will apply to both bempedoic acid and the combination product of bempedoic acid/ezetimibe. It is anticipated that most patients will be on the combination product. NICE does not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year (or £9,000 per 100,000 population). A query was raised about how this would impact and be managed within primary care as it could create considerable additional work. It was confirmed that no active searching is required to identify potentially suitable patients – it will be another option for patients who meet the NICE criteria. The committee approved the amendment of the formulary entries for bempedoic acid and bempedoic acid/ezetimibe to GREEN on both joint Formularies. Post meeting note: NICE guidance (https://www.nice.org.uk/guidance/ta694) recommends use of bempedoic acid in combination with ezetimibe; bempedoic acid is not recommended for use alone (i.e. without co-prescription of ezetimibe) or in combination with statins. **EQIA Assessment:** Yes, but a positive impact, as it would allow patients easier access to treatment with bempedoic acid with hopefully subsequent reductions in LDL-C and improved cardiovascular outcomes. **BLMK CCG E and D Lead comment:** Amendment to the joint medicines to prescribe Bempedoic Acid by primary care is likely to have a positive impact. This is not a policy change or changing service provision that would require full Equality Impact Assessment.	

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5.5	**Osteoporosis guideline update** Changes to the existing pathway have been made to incorporate the newly NICE recommended treatment option, romosozumab. NICE has approved romosozumab as an option for treatment of osteoporosis in people after menopause who are at high risk of fracture, only if: • they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture) This information has been added to stage 3 Specialist referral section of algorithm A (main osteoporosis algorithm) - romosozumab is for specialist use only and not for GP prescribing. Additional information has also been added to page 15 of the notes section, to reiterate that if romosozumab (or teriparatide, another secondary care treatment option, or denosumab) are started, the Specialists should inform GPs and any previous bisphospohonate treatment should be discontinued. The National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) have produced some guidance to support the implementation of the NICE guidance on romosozumab which includes additional information e.g. on T-scores. It was agreed that a link to the NOGG/ROS guideline does not need to be added to the Osteoporosis pathway as this is only relevant to specialists reviewing/selecting patients who may be suitable for treatment with romosozumab. Following completion of the 12 month course of romosozumab, specialists will assess the patient for ongoing treatment recommendations e.g. treatment with oral/IV bisphosphonate, or an alternative treatment (such as denosumab). Minor formatting errors and some typos were highlighted, which will be corrected by the author prior to finalising the document. A suggestion was also made that contact details for the clinical teams should be generic, rather for individuals, to ensure that communications are not missed in the absence of the named individuals. The committee discussed that Scriptswitch/Optimise message wording will need to be considered to ensure that the message regarding stopping bisphosphonates when romosozumab treatment is started is made clear. SMcG to work with NW, MN and KR to determine the best wording to provide this information to primary care prescribers. The committee discussed that lots of patients are transferred between osteoporosis treatments and within one GP practice they normally write a note on the Calcium/Vitamin D supplements to document what alternative treatment the patient is having, e.g. denosumab, IV bisphosphonate, as this helps provide a failsafe to ensure it is clear to prescribers that the patient is on an osteoporosis treatment which is not being prescribed by the practice.	SMcG SMcG/ NW/MN/ KR

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	A wider discussion then ensued around the recording of medicines prescribed by other services, e.g. HIV medicines, biologics, as this issue is not restricted to osteoporosis treatments. There is a mechanism to record medicines as hospital prescribed medicines within SystmOne (S1), though this is not particularly well used as many are not aware of it. The committee was informed that a document has previously been produced by the Medicines Optimisation team on documentation of hospital prescribed medicines which can be recirculated to practices to inform prescribers of the relevant mechanisms available within S1 to record medicines being prescribed by hospital/specialist services. The committee approved the updated treatment pathway with the amendments discussed at the meeting. **EQIA Assessment:** Yes, this will have a positive impact on patients with a high fracture risk (criteria as outlined by NICE) **BLMK CCG E and D Lead comment:** Guidelines for Primary Care to update Osteoporosis pathway does not require Equality Impact assessment because proposed changes are to an existing pathway. Both treatments are specialist use only and no GP prescribing. The initial stage treatment plan is applicable to all patients who fit the criteria. The changes are not significant to assess equality impact.	MD
5.6	**Potassium binders treatment pathway** The committee discussed the Hertfordshire and West Essex (HWE) potassium binders treatment pathway, to consider whether this could be adopted for use for relevant patients within BLMK. The renal specialist team at East and North Herts NHS Trust (ENHT) had requested that the pathway was reviewed for adoption within BLMK to allow a single treatment pathway to be utilised for all patients being managed by their service. Patients from Bedfordshire and Luton are generally under the care of renal specialists at ENHT, and patients from Milton Keynes are generally under the care of renal specialists in Oxford. Currently, locally, both potassium binders (sodium zirconium cyclosilicate (SZC) and patiromer) are recommended for use as per the recommendations by NICE and for specialist prescribing only – RED on both joint formularies. This was on the basis that, for treatment of persistent hyperkalaemia only, as this is a new drug, clinical experience can be gained by specialists with a potential reconsideration of an amended prescribing recommendation to follow. HWE Area Prescribing Committees have recently reviewed their prescribing recommendations at the request of local specialists and approved the treatment pathway for potassium binders. ENHT renal and cardiology teams consider that the clinical experience gained now supports a review of prescribing recommendation to AMBER INITIATION (Hertfordshire Formulary	

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	designation – equivalent to AMBER / AMBER 3 on the local joint Formularies) for the treatment of persistent hyperkalaemia only. A pathway has been approved within HWE to support the safe transfer of prescribing and monitoring requirements to primary care for both patiromer and sodium zirconium cyclosilicate following stabilisation by specialists. The reported information on experience gained from a relatively low number of patient initiation and continuation (approx. 10 patients) by ENHT renal and cardiology teams notes that selected patients who meet NICE criteria, are dose optimised (RAAS inhibitor and potassium binder) and stabilised usually at 4-6 weeks, after which monitoring frequency is aligned with that for RAAS inhibitor (RAASi) medication (e.g. ACEi, ARB) monitoring already embedded in clinical practice. In practice the majority of patients do not require dose adjustment of potassium binders following stabilisation, and stabilisation usually occurs 4-6 weeks after initiation of treatment. ENHT report similar experience from other sites using the potassium binders and that current prescribing recommendations have been considered a barrier for initiation and follow-up of patients. It is expected patient numbers may increase if continuation of care arrangements with primary care are put in place. The proposed pathway is line with the NICE TA recommendations and addresses the responsibilities at initiation and stabilisation in secondary care/specialists for patient selection, dosing adjustments and monitoring. Following on, the document supports primary care with ongoing prescribing and includes advice on monitoring frequency and 'red flags' where urgent action/contact with/escalation to specialist teams is required. The committee was asked to consider the detail of the pathway and if this supports sufficiently the safe transfer of prescribing and monitoring responsibility to primary care following stabilisation by specialists and thus consequently an amendment from RED traffic light status. Communication with the Oxford renal team indicated that, at the current time, they have started few patients on potassium binders for the management of chronic hyperkalaemia and are currently retaining prescribing within the hospital for these patients. This may be subject to review. The committee discussed the following: The guidance will not apply to patients from the Milton Keynes area under the care of the Oxford specialists at the current time. The Oxford specialist renal team currently retain prescribing of potassium binders but will be exploring changing this within their ICS (Buckinghamshire, Oxfordshire & Berkshire West (BOB)). The current costs of the potassium binders from the drug tariff indicate that at lower doses SZC is cheaper, but at higher doses patiromer is cheaper (due to 'flat' pricing of available patiromer	

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	strengths). Experience within the ENHT renal team to date has indicated that few patients are likely to require the dose of SZC to be increased from 5g to 10g, so this will mitigate the cost concerns. It was acknowledged that there is a potential cost pressure with increased doses of SZC, though at 5g it is cheaper than patiromer. Cardiology opinion from Bedfordshire Hospitals Trust on the pathway was still awaited, although interest has been expressed in prescribing potassium binders, therefore the pathway could potentially only be agreed for patients under the care of the Hertfordshire Trusts It was queried whether there is anything which the GP should do if they find that they are needing to increase the dose, to avoid an emergency admission (for potassium levels >6.5 mmol/L). If the dose only needs to be increased gradually then the GP can likely manage this. However, they may need to consult with the specialist if potassium levels are rising more rapidly, and/or consider other factors such as low-potassium diet, other medicines which may be affecting potassium levels or adjusting the dose of ACE/ARB. Similarly, if potassium levels reduced below 3.8, potassium binders may need to be discontinued with monthly monitoring of potassium levels and consideration of the continued suitability of the patient for treatment with ACE/ARB. To remain RED on MK formulary at present, pending review within the Oxford renal team/BOB ICS. AMBER on Bedfordshire/Luton formulary for patients being seen at ENHT trust only (as cardiology feedback on the pathway from Bedfordshire Hospitals Trust was awaited), in line with the HWE pathway. **EQIA Assessment:** Yes, but a positive impact as this would allow easier access to treatment for patients with chronic kidney disease (or heart failure) **BLMK CCG E and D Lead comment:** What is proposed in the document for consideration would require a close monitoring of patient safety and impact assessment. The information is not clear to make judgement if this requires a full Equality Impact Assessment or not. Suggestion – if treatment pathway is approved then regular monitoring of impact should be put in place.	
5.7	**Buccal midazolam prescribing guidance** The preparations of buccal midazolam available on the joint Formularies was reviewed at the last meeting of the Formulary Subgroup (FSG) on 7th June 2022. The FSG agreed the brands / presentations of buccal midazolam which would be available on the Formularies, as follows: • Buccolam remains first line choice of buccal midazolam for all new patients (children and adults).	

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	• Epistatus pre-filled syringes to be removed from the Formularies for new prescriptions – retained for existing patients only. • Epistatus multidose bottle (unlicensed) to be added to both Formularies for patients who cannot receive a fixed dose from a pre-filled syringe e.g. young children being dosed on a mg/kg basis (Amber/Amber 1). • Epistatus multidose bottle (unlicensed) added to Milton Keynes Formulary only for use in emergency trays and pre-operative sedation (RED). Following on from this, it has been necessary to update the previously agreed Bedfordshire & Luton Joint Prescribing Committee (JPC) prescribing guidance for buccal midazolam, and it was proposed that amended guidance is adopted for use across BLMK. The committee discussed the guidance, and it was noted that there was a significant amount of historical information included from Bedfordshire and Luton JPC but no equivalent information from MK. This makes it less clear that the current document will apply to the whole of BLMK. It was clarified that there was good representation, and contribution, from MK representatives for the FSG discussion on buccal midazolam. It was suggested that the current document should be reformatted to ensure it is clear that it will be for use across BLMK, with historical information being moved e.g. to an appendix. The committee approved the prescribing guidance, with reformatting of the document as discussed at the meeting. This will then be forwarded to the Chair for approval by Chair's action. **EQIA Assessment:** No impact anticipated **BLMK CCG E and D Lead comment:** This is likely to have a positive impact on patients. Equality impact assessment is not needed as this is not a new treatment. Suggest – regulator monitoring for impact.	TL/HC/ CC
5.8	**Shared Care Guideline template update** At the March 2022 APC an AOB discussion was undertaken with the proposal of an update to the wording of the shared care guideline template. This was around the completion of appendix 1 by the Specialist. The committee discussed the practicalities and some medicolegal considerations. It was proposed that the Appendix 1, section A should be removed as completion of this requires significant additional work by the specialists and the information is included in the clinic letters which accompany the shared care guideline, however some medicolegal concerns remained from primary care representatives. There is a governance framework within the Trusts to ensure that clinic letters have an audit trail documenting their electronic approval. It was requested by primary care representatives that GP actions, including the request to undertake shared care, should be made extremely clear within the clinic letter.	

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	The principal changes made were: • Appendix 1 has been changed to offer the Primary Care Providers some examples of reasons where shared care arrangements may not be accepted. • Removal of the need for the Specialist to complete an additional form to advise the Primary Care Prescriber of the information relating to individual patients. This is because, this information is included in clinic letters and there is an audit trail documenting any electronic approval of these letters. • Removal of the requirement for the Primary Care Prescriber to complete a form to advise that they are declining shared care. This must still be done in writing via letter or appropriate electronic communication within the specified timescales. • Addition of the information that as the patient is a partner in the shared care arrangement, where appropriate, the patient should be provided with access or direction to a copy of the current shared care guideline. In advance of the meeting, some formatting amendments and minor changes to wording were suggested which will be incorporated into the document prior to it being finalised. These comments were circulated to committee members prior to the meeting. A comment was also received in advance of the meeting suggesting that a caveat should be added to allow termination of shared care in primary care, and referral back to secondary care, due to lack of patient engagement (very rare occurrence). This was supported by the committee; however the committee also discussed that patient partnership with shared care was vital to its success and that it is important to get feedback from the patient to ensure that the patient understands fully regarding the shared care process and that this is not the reason for non-engagement with shared care. Communication to the patient at the beginning, and throughout shared care, is crucial to ensure that the patient understands fully all the practicalities of the shared care. Not all patients will be proactive in participating in the shared care e.g. ensuring that blood tests are done when required. A leaflet could be developed to help inform patients about shared care – this would be a generic leaflet which could be adapted by different specialities. There was also a discussion regarding whether the patient should be asked to sign to confirm their consent for shared care, but it was agreed this did not need to be mandated in the template (although some clinical teams do ask patients to sign when the medicine/ shared care information is being provided) as the consent will always be documented in the patient's notes. The committee discussed how patients from out of the BLMK area e.g. treated at BHFT, but lives in Northamptonshire, should be managed and what the best process is for approaching this situation.	

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	It was clarified that in BLMK, we advocate following the SCG of the initiating trust, unless the information is unclear or appears to be unsafe, but we cannot mandate this within other areas. If problems are being experienced in a particular area, the Medicines Optimisation team can raise this with the relevant CCG to try and resolve the issue. JC to write a draft patient information leaflet and liaise with MC and CG on the content. The committee agreed the updated Shared Care Guideline template, with the amendments agreed at the meeting. **EQIA Assessment:** not assessed – procedural document **BLMK CCG E and D Lead comment:** N/A	JC JC
6.0	**NICE Guidance – from 21st April 2022 until 15th June 2022** **The following NICE Technology Appraisal Guidance (CCG Commissioned) have been published:** **Romosozumab for treating severe osteoporosis** Technology appraisal guidance [TA791] Published: 25 May 2022 https://www.nice.org.uk/guidance/ta791 Using NICE assumptions, the BLMK cost impact of introducing the guidance is approximately £67.5k in 2022/23, rising to £450k by year 5. However, savings are anticipated from potential fractures avoided. **APC actions –** created and link added to Formularies (RED traffic light on both Formularies). Discussed under agenda item 5.5. **Filgotinib for treating moderately to severely active ulcerative colitis** Technology appraisal guidance [TA792] Published: 01 June 2022 https://www.nice.org.uk/guidance/ta792 NICE Resource Impact Statement: NICE do not expect this guidance to have a significant impact on resources. **APC actions –** link added to Formularies (RED traffic light on both Formularies). Discussed under agenda item 5.3. **The following NICE Guidelines (NG) (Medicine related and CCG Commissioned) have been published / updated by NICE:** **Epilepsies in children, young people and adults;** NICE guideline [NG217] Published: 27 April 2022 https://www.nice.org.uk/guidance/ng217	

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	This guideline covers diagnosing and managing epilepsy in children, young people and adults in primary and secondary care, and referral to tertiary services. It aims to improve diagnosis and treatment for different seizure types and epilepsy syndromes, and reduce the risks for people with epilepsy. This guideline updates and replaces NICE guideline CG137 (January 2012). **APC action**: review Formulary status of anti-seizure medications **Gout: diagnosis and management;** NICE guideline [NG219] Published: 09 June 2022 https://www.nice.org.uk/guidance/ng219 This guideline covers the diagnosis and management of gout. It includes recommendations on diagnosing gout, managing flares, long-term management of gout and referral to specialist services. **APC action:** review need for gout treatment pathway (note, there is a LDH Hospital Algorithm for acute management of Gout currently available via the Bedfordshire/Luton Formulary) **Preterm labour and birth NICE guideline**; [NG25] Published: 20 November 2015 Last updated: 10 June 2022 https://www.nice.org.uk/guidance/ng25 This guideline covers the care of women at increased risk of, or with symptoms and signs of, preterm labour (before 37 weeks), and women having a planned preterm birth. It aims to reduce the risks of preterm birth for the baby and describes treatments to prevent or delay early labour and birth. In **June 2022**, NICE made new recommendations on the use of repeat courses of maternal corticosteroids. For further details see update information. **APC action:** none – changes secondary in recommendations would apply in secondary care only **The following COVID 19 related information has been produced/updated by NICE:** **COVID-19 rapid guideline: managing COVID-19 NICE guideline [NG191]** Published: 23 March 2021 Last updated: 06 May 2022 https://www.nice.org.uk/guidance/ng191 This guideline covers the management of COVID-19 for children, young people and adults in all care settings. It brings together NICE's existing recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily. On **6 May 2022**, NICE added new recommendations on baricitinib. On **19 May 2022**, NICE replaced 2 recommendations about advice to give to people with COVID-19 with a single recommendation linking to the UK Health Security Agency's guidance for people with symptoms of a respiratory infection including COVID-19, which now provides this information. We deleted the recommendation for people with pre-existing advanced comorbidities because finding out whether they have advance care plans or advance decisions to refuse treatment is part of routine care.	AG/TL AG/MN

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	The following NICE TAs are the commissioning responsibility of NHSE and are listed for information only: **Venetoclax with low dose cytarabine for untreated acute myeloid leukaemia when intensive chemotherapy is unsuitable** Technology appraisal guidance [TA787] Published: 27 April 2022 https://www.nice.org.uk/guidance/ta787 **APC action**: link added to Formularies **Tucatinib with trastuzumab and capecitabine for treating HER2-positive advanced breast cancer after 2 or more anti-HER2 therapies** Technology appraisal guidance [TA786] Published: 27 April 2022 https://www.nice.org.uk/guidance/ta786 **APC action**: Created (Tucatinib) and link added to Formularies **Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 and over** Highly specialised technologies guidance HST20 Published: 05 May 2022 https://www.nice.org.uk/guidance/hst20 **APC action**: consult with acute trusts to determine whether this will be used locally and needs to be added to the local formularies. MKUH confirmed that there are no children under the care of MKUH with this condition therefore Selumetinib is unlikely to be used. No response was received from BHFT however, as this is a highly specialised technology, it is unlikely there will be any local prescribing. It was proposed, and agreed, that there should be no addition to local formularies. **Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy** Technology appraisal guidance [TA788] Published: 11 May 2022 https://www.nice.org.uk/guidance/ta788 **APC action**: link added to Formularies **Tepotinib for treating advanced non-small-cell lung cancer with MET gene alterations** Technology appraisal guidance [TA789] Published: 18 May 2022 https://www.nice.org.uk/guidance/ta789 **APC action**: Created and link added to Formularies **Ibrutinib for treating Waldenstrom's macroglobulinaemia** Technology appraisal guidance [TA795] Published: 08 June 2022 https://www.nice.org.uk/guidance/ta795 **APC action:** none (not recommended) **Diroximel fumarate for treating relapsing–remitting multiple sclerosis** Technology appraisal guidance [TA794] Published: 08 June 2022 https://www.nice.org.uk/guidance/ta794 **APC action**: created and link added to Formularies	

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	Anifrolumab for treating active autoantibody-positive systemic lupus erythematosus (terminated appraisal) Technology appraisal [TA793] Published: 08 June 2022 https://www.nice.org.uk/guidance/ta793 **APC action:** none (terminated appraisal) **Enfortumab vedotin for previously treated locally advanced or metastatic urothelial cancer (terminated appraisal)** Technology appraisal [TA797] Published: 15 June 2022 https://www.nice.org.uk/guidance/ta797 **APC action:** none (terminated appraisal) **Venetoclax for treating chronic lymphocytic leukaemia** Technology appraisal guidance [TA796] Published: 15 June 2022 https://www.nice.org.uk/guidance/ta796 **APC action**: link added to Formularies The committee noted that the Final Appraisal Document for "Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs" has been published, with expected final publication date for the TA of 13 July 2022. There is 30 day implementation for this TA. It was proposed that Risankizumab for active psoriatic arthritis will be added to the joint Formularies within the 30 day period, and an updated Psoriatic Arthritis pathway will be presented at APC in September. The lack of updated pathway will not prevent clinicians from prescribing Risankizumab for eligible patients, as per NICE guidance, in the interim. The committee agreed this approach.	JC
7.	**Medicines Safety update** A Primary Care Medicines Safety Update and a Medicines Safety Group (MSG) Update was presented to the committee. **Primary Care Medicines Safety Update** This update focussed on the primary care response to the MHRA Drug Safety Updates (May and June 2022). In particular: **Denosumab 60mg (Prolia): should not be used in patients under 18 years due to the risk of serious hypercalcaemia** Serious and life-threatening hypercalcaemia has been reported with denosumab 60mg (Prolia) in children and adolescents in clinical trials for osteogenesis imperfecta and during off-label use. Denosumab 60mg (Prolia) is authorised for use in adults with osteoporosis and other bone loss conditions – it should not be used in children and adolescents younger than 18 years. **Action(s) taken:** DSU included in BLMK primary care newsletter to inform primary care to refer in patients to their specialist if they encounter any patients under 18 prescribed Denosumab 60mg (Prolia) as it should not be used in children and adolescents younger than 18 years. Denosumab 120mg (as Xgeva) remains authorised for skeletally mature adolescents with giant cell tumour of bone (alongside other authorisations – see MHRA DSU for more	

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	information). Clinicians encouraged to report any suspected adverse drug reactions associated with denosumab or other medicines on a Yellow Card. To review numbers within primary care and at acute trusts. Trust MSOs confirmed the MHRA DSU will be disseminated to relevant clinical teams. It was noted that osteoporosis treatment with denosumab is associated with hypocalcaemia, not hypercalcaemia which seems to be limited to the osteogenesis imperfecta indication. There is therefore no need for wider concern about this. Hypercalcaemia seems to be associated with osteogenesis imperfecta (OI) because of the abnormal bone turnover and is particularly associated with the more severe forms of OI (types 4 or 7) rather than the milder forms (such as types 1 and 3). **Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk** Decreased vitamin B12 levels, or vitamin B12 deficiency, is now considered to be a common side effect in patients on metformin treatment, especially in those receiving a higher dose or longer treatment duration and in those with existing risk factors. The MHRA are therefore advising checking vitamin B12 serum levels in patients being treated with metformin who have symptoms suggestive of vitamin B12 deficiency. They also advise that periodic monitoring for patients with risk factors for vitamin B12 deficiency should be considered. **Action(s) taken**: DSU to be disseminated to primary care commissioning for information and diagnostics and to be circulated via BLMK primary care newsletter to raise awareness. To be discussed at next MSG r.e dissemination to relevant clinical teams. RS requested to be involved in any discussions about the monitoring of vitamin B12, and DW agreed to include him in the discussions with planned care/primary care. **Roche Accu-Chek Insight insulin pump with NovoRapid PumpCart insulin cartridges: alert following cases of insulin leakage** The Accu-Chek Insight Insulin pump used with NovoRapid PumpCart prefilled insulin cartridges has been associated with insulin leakage events, including cases of severe hyperglycaemia and diabetic ketoacidosis in UK patients. **Action(s) taken:** A National Patient Safety Alert has been issued including actions to identify and review patients using Roche Accu-Chek Insight insulin pumps and discuss moving them to an alternative insulin pumps where possible, pharmacists should continue to dispense the NovoRapid PumpCart cartridges but ask patients whether they use the Accu-Chek Insight insulin pump and provide advice and education to minimise the risks (as below), report suspected adverse drug reactions or adverse incidents to the Yellow Card scheme – DSU to be included in the primary care newsletter	

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	and flagged to relevant CCG/ICB key stakeholders. To confirm at next MSG that trust clinical teams and integrated clinical teams have been notified. For review at the next MSG. **<u>Medicines Safety Group Update</u>** **Dissemination of DSUs:** The DSUs for March and April 2022 for dissemination to key stakeholders via our local provider MSOs for cladribine (new advice to minimise serious liver injury) and Amiodarone (reminder of risks of treatment and need for patient monitoring and supervision) has been actioned – this was confirmed at MSG. DSUs for May and June to be discussed at next MSG meeting. **Medicines safety interventions and project update:** **Potassium permanganate (topical) - inadvertent oral administration https://www.england.nhs.uk/publication/national-patient-safety-alert-inadvertent-oral-administration-of-potassium-permanganate/ for action by October 2022** has been reviewed at the most recent BLMK formulary subgroup. Potassium permanganate is to remain on Formulary with optimisation of safety messaging on all platforms (Formulary/Scriptswitch/Optimise Rx /Newsletters) to highlight the risk of inadvertent ingestion and terminology used in the NPSA alert. **Midazolam prescribing for paediatric patients in primary care** has been reviewed in terms of formulary alignment, by the BLMK formulary subgroup. The Epistatus multi dose bottle has been added to Formularies (unlicensed) for use where non-standard dosing is required (Amber 1/Amber). Separate entry for Milton Keynes to reflect RED uses (pre-op and emergency trays). Move all Epistatus pre-filled syringe strengths to Non-Formulary, existing patients only – Buccolam to be used as first line product (licensed). Next steps to work with community providers and primary care on communication particularly on updating the information that flags to GPs when they select midazolam on their prescribing system. **Sodium valproate project update** – MSG are compiling a list of specialist team contact details to support clinicians to signpost patients whom require an annual review to be assessed in line with the pregnancy prevention programme, to the appropriate service given the clinical indication. BLMK MSG newsletter to do a theme on drugs in pregnancy with main feature Sodium valproate pregnancy prevention programme. The recent MHRA updates on metformin and pregabalin and reminder of sodium valproate will be included within this prospective BLMK medicines safety newsletter, it is acknowledged that this information has also been disseminated via the BLMK APC newsletter. **Group membership:** The MSG are looking to open expressions of interest for more members to be opted into the group, specifically	

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	primary care network representation and also consideration of community pharmacy involvement (to be discussed at a future meeting). The group will have health and justice representation from July onwards.	
8.	**Formulary Update**	
8.1	**Formulary Subgroup Recommendations** The following recommendations were made by the Formulary subgroup at the 7th June 2022 meeting: <u>Otigo Ear drops for otitis media</u> Do not support the use of Otigo ear drops for use in Otitis Media due to insufficient evidence to support efficacy & proposed reduction in antibiotic consumption. <u>Potassium permanganate review of Formulary positions</u> Retain position (GREEN) with dissemination of information and strengthening of safety warnings on the Formularies. <u>Gonadorelin Formulary Review</u> Addition of all gonadorelin preparations on the Formularies as Amber/Amber 1 with link to the table of licensed indications tool. <u>Buccal midazolam for Status Epilepticus</u> • Remove Epistatus pre-filled syringes from the Formulary for new prescriptions – retained for existing patients only. • Addition of Epistatus multidose bottle (unlicensed) for patients who cannot receive a fixed dose from a pre-filled syringe (Amber/Amber 1). • Addition of Epistatus multidose bottle (unlicensed) to Milton Keynes Formulary only for use in emergency trays and pre-operative sedation (RED). <u>Tizanidine for spasticity in Multiple Sclerosis</u> Addition of only the 2mg strength tizanidine to Formularies (Amber/Amber 3). <u>Agomelatine for major depression</u> Retain status quo (i.e. RED Restricted) on the Bedfordshire/Luton Formulary pending further discussions around possible shared care. Milton Keynes to update Formulary entry from non-formulary to Red in line with Bedfordshire/Luton. It was raised that agomelatine is currently non-formulary for CNWL and therefore it does not seem appropriate for the system (MK) formulary to be more lenient than the specialist formulary. It was confirmed that although agomelatine is used occasionally by CNWL, it is currently listed as non-formulary on the CNWL formulary. RAk to take up this issue up within CNWL. TL to follow up with RAk. <u>Actimorph addition to Formulary for pain</u> Addition of Actimorph (GREEN) to Formularies as another option for treating pain.	RAk/TL

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	The committee discussed the reasons for the addition of actimorph to the joint Formularies and it was confirmed it has been added in response to problems experienced in primary care e.g. patients spilling oramoprh liquid, taking doses without measuring correctly. The addition of actimorph to the joint Formularies will be fed back to the pain team at MKUH, alongside the reasons for the addition. <u>Narcolepsy and cataplexy pathway</u> • Change Modafinil - Non-Formulary to Amber SCG • Add Methylphenidate, Dexamphetamine – Amber SCG • Add Clomipramine, venlafaxine – Amber / Amber 3 • BLMK is located between 4 tertiary sleep centres (Papworth, Guy's, Oxford & Leicester) which have different SCGs – to use SCG from which the patient was referred in the interim. <u>Progesterone pessaries breach</u> • BLMK CCG made aware of a breach in prescribing. Patient sent to GP for continuation of progesterone pessaries (RED Formulary status) from EPAU. • A reminder that RED drugs are not for prescribing in Primary care and any breaches will be treated as an incident. • Other CCGs have moved progesterone pessaries to Amber – for future review. • Further discussion - updated RCOG guidance to be reviewed. Highlighted it is not clear that patients need to have a uterine pregnancy confirmed via scan. Possibly some patients being prescribed in primary care prior to receiving a scan. Further discussions within Medication Safety workstreams around this. • Need for robust breach process highlighted – to take forward as a project with secondary care. Decision: Retain RED Formulary status until further review. <u>Chlordiazepoxide (Librium) warning (for noting)</u> • The MHRA has been made aware of concerns raised following changes to the product information for chlordiazepoxide (Librium) regarding a possible genotoxicity risk and contraception requirements for males and females. This relates to recent implementation of the European Medicines Agency's SWP recommendations in relation to genotoxic medicines. • Approximately 61 patients in BLMK. • Healthcare professionals should continue to use current clinical guidelines while this issue is being evaluated. **Minor Formulary updates (for noting)** • Sitagliptin now first line DPP4 inhibitor in line with the current Prescribing Incentive Scheme. • Haloperidol 500mcg tablets removed due to large price rise. Now recommending oral solution as alternative. • Rinatec has updated brand name to Rinaspray – Formulary updated (currently unavailable).	

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	• Elleste Solo MX patches have been discontinued. The committee ratified the recommendations of the Formulary Subgroup.	
8.2	**Wound Management Formulary Steering Sub-Group Recommendations** The Emollient section of the Bedfordshire and Luton wound management formulary has been updated to reflect current practice in the community as well as prescribed products. Previous wording had given the impression that Zeroderm range was the preferred product, however this range is not available via the NHS Supply Chain, the procurement portal for items on the Wound Management Formulary. Epaderm is a cost-effective product available via NHS Supplies. This was not correctly reflected on the Formulary but has now been updated. NB – this applies to the Wound Management Formulary (Beds and Luton) only. The Zeroderm range of products remain the preferred products on both of the joint Medicines Formularies. The committee ratified the recommendations of the Wound Management Steering subgroup.	
9.	**Antimicrobial Resistance Update** The BLMK AMR / HCAI steering group met on the 23rd June 2022. The steering group was joined by the NHS England Regional Antimicrobial Stewardship Lead for the East of England, Naomi Fleming. Regional antimicrobial prescribing data indicates (for East of England): • Low total antibiotic prescribing in secondary care but higher than average use of IV and broad spectrum (watch and reserve) antibiotics • Primary care prescribing reflects national trends The committee noted the information presented.	
All other papers (from this point in the agenda) are for noting/information by the Committee		
10.	**East of England Priorities Advisory Committee (EoEPAC) – items for noting/approval**	
10.1	EoEPAC Meeting Notes – January 2022 The committee noted the minutes for information.	
10.2	EoEPAC draft Meeting Notes – March 2022 The committee noted the minutes for information.	
10.3	**EoEPAC IQoro neuromuscular training device** The committee reviewed the EoEPAC recommendations for the IQoro neuromuscular training device. When used along with an associated exercise regime, known as IQoro training, it has been advocated to strengthen the muscles of the oropharynx, oesophagus	

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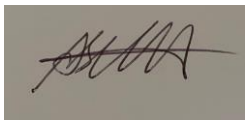
	and diaphragm. The PAC recommendations have previously been circulated to clinicians for comment in 2021. IQoro was added to the drug tariff in May 2022, and therefore is now available for prescribing on FP10. There has been no significant change to the evidence base since original circulation. IQoro is not recommended for stroke related dysphagia, hiatus hernia or any other uses due to the limited evidence to support the use of IQoro. The effect of IQoro compared with NHS standard care or spontaneous improvement remains unclear. The committee ratified the EoEPAC recommendations for IQoro.	
11.	**Bedfordshire, Luton and Milton Keynes Local Prescribing Committee Minutes.** The Committee noted the following minutes for information.	
11.1	Minutes from the Bedfordshire Hospitals Foundation Trust DTC meeting – April 2022	
11.2	Minutes of the Milton Keynes Hospital Prescribing & Medicines Governance Committee (PMGC) – April 2022	
11.3	Minutes of the Bedfordshire and Luton Formulary Subgroup – April 2022	
11.4	Minutes of the Bedfordshire and Luton Wound Management Formulary Steering Group – March 2022	
11.5	CNWL - Trustwide Medicines Optimisation Group (MOG) Meeting Minutes – February 2022	
12.	**Papers for information / ratification** Interim clinical commissioning policies for COVID-19	
12.1	**Interim Clinical Commissioning Policy: Antivirals or neutralising monoclonal antibodies for non-hospitalised patients with COVID-19** (Version 6), published 30th May 2022 (and associated clinical guide). https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103208 Updated national interim clinical commissioning policy, effective from 13 June 2022 **Key changes:** • Updated 'highest risk' cohorts, in accordance with Independent Advisory Group recommendations. • Different criteria for adults (aged 18 years and over) and children (aged 12-17 years) • Nirmatrelvir/ritonavir (Paxlovid) may be considered as a treatment choice for patients with stage 3 chronic kidney disease (CKD 3), subject to adequate arrangements for dose adjustment • Local policies and procedural paperwork, including GP referral via S1, have been updated accordingly. Implemented by the CMDU from 13 June 2022.	

No	Agenda Item	Action
	The committee ratified the update to the Interim Clinical Commissioning Policy.	
12.2	**Baricitinib for patients hospitalised due to COVID-19** The committee noted this new policy, which makes Baricitinib available as an additional treatment option for patients admitted to hospital to manage the symptoms of COVID pneumonia.	
12.3	**Interim Clinical Commissioning Policy: Antivirals or neutralising monoclonal antibodies in the treatment of hospital-onset COVID-19 (Version 7)** The committee noted version 7 of the policy, which includes updated 'highest risk' cohorts of patients who are potentially eligible for COVID treatments, in accordance with Independent Advisory Group recommendations, effective from 13 June 2022.	
13.	**Any other business** Modified release (MR) tramadol preparations are currently non-formulary on both joint Formularies. However, these products are being widely prescribed and offer some benefits to the patient as they need to be taken less frequently than standard release tramadol and there is lower potential for abuse. The committee agreed to the addition of tramadol MR to the joint Formularies (GREEN traffic light). The Chair advised the committee that the agenda for September is already looking very full and therefore some papers may be circulated virtually in advance of the meeting. The Chair requested that responses are returned in a timely fashion when papers are circulated as this will aid the smooth running of the meeting on 28th September.	
14.	**Future Dates for BLMK APC 2022/23 Meetings:** Wednesday 28th September 2022 - 12.30-3.00pm Wednesday 7th December 2022 - 12.30-3.00pm Wednesday 1st March 2023 - 12.30-3.00pm Wednesday 3rd May 2023 - 12.30-3.00pm Wednesday 5th July 2023 - 12.30-3.00pm Wednesday 27th September 2023 - 12.30-3.00pm Wednesday 6th December 2023 - 12.30-3.00pm	

Approval of minutes:

Chair: Alison Borrett

Signed: 

Date: 14/10/22

Appendix 1 – Approved 7th June 2022 Formulary Subgroup Minutes:

FSG Final Minutes 7.6.22_Signed by JF.d