**Bedfordshire, Luton, and Milton Keynes Area Prescribing Committee – Formulary Subgroup meeting**

**Meeting Notes**

Date: 4th February 2025

Time: 12.30 - 14.00pm

Venue: Microsoft Teams

**The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust**

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| **Name** | **Initial** | **Role** | **Present** | **Absent** |
| Fiona Garnett | FG | Committee Chair |  |  |
| Samina Hassanali | SH | Professional Secretary/Formulary & Medication Safety Pharmacist, NHS BLMK ICB |  |  |
| Janet Corbett | JCo | Pharmacy Programme Manager MKUH |  |  |
| Saema Arain | SA | ELFT Pharmacy Representative – Community Services (Beds)/Mental Health Services (Beds and Luton) |  |  |
| Prabjoth Kaur | PK | Lead Pharmacist Medicines Information and Formulary |  |  |
| Dr Mya Aye | MA | Medical Representative, Milton Keynes University Hospital |  |  |
| Dr Eleanor Tyagi | ET | Medical Representative, Milton Keynes University Hospital |  |  |
| Carole Jellicoe | CJ | Nurse and Non Medical Prescribing Representative (Secondary Care) |  |  |
| Nikki Woodhall | NW | MK Place lead Medicines Optimisation & digital transformation lead |  |  |
| Dr Kate Randall | KR | GP Representative, Bedfordshire and Luton |  |  |
| Dr Jenny Wilson | JWi | GP Representative, Bedfordshire and Luton |  |  |
| Reginald Akaruese | RA | CNWL Pharmacy Representative (Community and Mental Health Services Milton Keynes) |  |  |
| Mojisola Adebajo | MA | Place Based Lead Pharmacist BLMK ICB, Luton |  |  |
| Matt Davies | MD | Head of Pharmacy and Medicines Optimisation and Place Based Lead Pharmacist, C Beds |  |  |
| Alex Hill | AH | Community Pharmacy Representative |  |  |
| Dr Dushyant Mital | DM | Medical Representative, Milton Keynes University Hospital NHS Trust |  |  |
| Marian Chan | MC | Consultant, Bedfordshire Hospitals NHS Foundation Trust |  |  |
| Qiratulain Khan | QK | Lead Pharmacist Medicines Information and Formulary |  |  |
| Anne Graeff | AG | Commissioning Lead Pharmacist BLMK ICB |  |  |
| Joy Mooring | JM | Primary Care Specialist Pharmacy Technician, BLMK ICB |  |  |
| Dona Wingfield | DW | Medicines Use and Quality Manager, Bedfordshire Hospitals NHS Foundation Trust |  |  |
| Anila Anwar | AA | Governance and Policies Pharmacist  Bedfordshire Hospitals NHS Foundation Trust |  |  |
| Iffah Salim | IS | Advanced clinical practice CAMHS Pharmacist  Neurodevelopmental Team, ELFT. |  |  |
| Nicholas Beason | NB | Procurement technician MKUH |  |  |
| Candy Chow | CC | Commissioning Lead Pharmacist BLMK ICB |  |  |
| Sandra McGroarty | SMc | Commissioning Pharmacist, BLMK ICB |  |  |
| Jonathan Walter | JWa | Milton Keynes GP representative |  |  |
| Dupe Fagbenro | DF | Deputy Chief Pharmacist (Luton and Bedfordshire)  East London NHS Foundation Trust |  |  |
| Maggie Winter | MW | Milton Keynes GP representative |  |  |
| Amjid Hussain | AHu | Bedfordshire Lead for the Community Mental Health Services, ELFT. |  |  |
| Sanil Patel | SP | Associate Director of Pharmacy MKUH |  |  |
| Jenny Cusack | JCu | General Practitioner and Menopause Specialist, Asplands Medical Centre and MKUH. |  |  |
| Clare Morlidge | CM | Consultant renal pharmacist, East North Hertfordshire NHS Trust. |  |  |
| Lianne Lewis | LL | Inflammatory Bowel Disease Nurse MKUH |  |  |

**Summary of acronyms used in the document**

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| **Acronym** | **Explanation** |
| MKF | Milton Keynes Formulary |
| B&LF | Bedfordshire and Luton Formulary |
| FSG | Formulary subgroup |
| ORx | Optimise GP messages |
| SCG | Shared care guidance |

| **No** | **Agenda Item** |
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| 1. | **Welcome, Introductions and Apologies**  The chair welcomed everyone to the meeting including Clare Morlidge, consultant renal pharmacist, East North Hertfordshire NHS Trust, Dr Cusack, General Practitioner and Menopause Specialist, Asplands Medical Centre, and Lianne Lewis, Inflammatory Bowel Disease Nurse, Milton Keynes University Hospital NHS Foundation Trust  Apologies received from Janet Corbett and Amjid Hussain.  The meeting was confirmed as quorate. |
| 2. | **Declarations of Interest**  Annual written declarations of interests – currently up to date and renewals required at the end of the month have been contacted.  Members were invited to declare any conflicts of interest relating to matters on the agenda, none declared. |
| 3. | **Minutes of the previous meeting**  The November 2024 FSG meeting notes were approved as accurate. |
| 4. | **Action Log**  Actions were noted in accordance with the action log:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Item** | **Title** | **Date added** | **Owner** | **Action** | **Update** | | | 1 | **Apomorphine shared care** | November 2024 | Samina | Contact details will be checked and completed.  Communication between care providers to be moved from patient responsibilities to specialist and primary care responsibilities.  Use wording from GMC regarding primary care taking on shared care. | Contact details checked and completed.  Communication responsibilities kept under patients and/or carer section and wording around primary care taking on shared care kept as per approved generic BLMK SCG template.  Following concerns at a place based prescribing group, domperidone prescribing will remain under the specialist. Closed. | | | 2 | **Temazepam and nitrazepam formulary status** | November 2024 | Samina | IS to take proposal to Med. Com. for comments. | Med com agreed to align with formulary status for BLMK for services in Luton/ Beds. Closed. | | 3 | **An update of bioequivalent options of methylphenidate** | November 2024 | ELFT | Update to <https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/guideline/table-of-available-brands-for-biphasic-methylphenidate-mr-products/> | In progress. |   The formulary pages will be updated with new methylphenidate preparations and bioequivalent options. |
| 5. | **Items for consideration** |
| 5.1 | **ADHD children and young people shared care guideline.**  This guidance has been updated using the BLMK SCG template for use across the ICS in collaboration with ELFT, CNWL and CCS providers. Updated contact information for specialist services has been included. There is now information on treatment breaks to consider individual circumstances and preferences. Shortages continue to be fluid and are anticipated to continue until at least April hence information on generic prescribing is available to support the selection of alternative bioequivalent products. ELFT have guidance on selecting appropriate alternatives (and this information can also be found on the formulary pages). Dexamfetamine has been included as it was an alternative option during the shortages but is not a common treatment option due to the three times a day dosing. The SCG now includes information on driving (as provided by the DVLA), pregnancy and breast feeding.  RA confirmed that this SCG has been circulated to the CAMHS consultants within CNWL for comment and he has met with them to discuss.  There was concern regarding the frequency of monitoring heights, weights, BP and pulse and the need to plot on a centile chart as there is no funding for managing these patients. It was also raised that children waiting to be transferred into adult services are solely managed by the GP and this duration can be significant. IS confirmed that physical observations should be completed every time a child is reviewed by the specialist and will be included in the letter to the GP. The frequency of monitoring depends on complexity and if the medication is being titrated, but stable patients are usually seen every 6-12 months, as is the recommendation for specialists. Most of the monitoring is done in the community, but there is a requirement that GPs ensure that this is happening and code the information onto the patient’s record to take the responsibility for safe prescribing as per NICE.  MD will take the monitoring for ADHD in younger children where 3 monthly, 6 monthly monitoring is required to the primary care framework group for consideration.  The shared care guideline was approved. |
| 5.2 | **Bupropion for depression** – deferred to next meeting |
| 5.3 | **Nephrotrans**  Lister Hospital cares for renal patients in Bedford and Luton and is part of East and North Herts Trust. Nephrotrans has been brought for consideration to the formulary group by CM as it has been approved for use in East and North Herts as a second line option and will allow equity in the treatment of all patients under the care of Lister renal unit.  NICE CKD guidelines (NG203 2021), state to consider oral sodium bicarbonate supplementation when eGFR <30ml/min/1.732 and a serum bicarbonate <20mmol/litre.  Sodium bicarbonate 500mg capsules are the first line formulary option and the most cost-effective preparation, the alternative 600mg tablets are significantly more expensive, and are therefore not on the formulary.  In patients who cannot tolerate sodium bicarbonate capsules due to side effects such as bloating and wind, treatment discontinuation leads to patients feeling unwell and clinicians struggle to get the bicarbonate back in range. Nephrotrans, sodium hydrogen carbonate 500mg gastro-resistant capsules, are suggested as a second line option for adults with chronic kidney disease (eGFR <30ml/min/1.732 and a serum bicarbonate <20mmol/litre). There is the potential for GPs to switch patients on sodium bicarbonate tablets to Nephrotrans for a cost saving of around £250 per patient per year.  Nephrotrans has been raised within the East of England renal network.  CM clarified that some dialysis patients, that don’t require three times a week dialysis, may require sodium bicarbonate but generally this treatment is for non-dialysis, non-transplant patients.  BHFT will check their costing for Nephrotrans, but most of the cost would be with primary care as the proposal is for amber status, for specialist initiation, stabilisation and then continuation by the GP.  To ensure that prescribing is second line and only to be initiated and stabilised by the renal specialists (SpIS), the wording on the Hertfordshire and West Essex area formulary will be incorporated and can be strengthened. Prescribers can also be dissuaded from the more costly 600mg tablets by making it non-formulary. The Optimise Rx team will be consulted for the potential to add a switch message for any current patients on sodium bicarbonate 600mg tablets to Nephrotrans, if the 500mg capsules have already been tried, and this switch is supported by the renal specialists.  The group agreed to add Nephrotrans to the formularies as SpIS, second line after sodium bicarbonate 500mg capsules. |
| 5.4 | **Liraglutide biosimilar**  Victoza® (liraglutide) is a GLP-1 receptor agonist and the originator product licensed for managing type 2 diabetes mellitus in adults, adolescents and children over 10 years old. Supply problems with GLP-1 RAs have been ongoing since June 2023. Novo Nordisk lost the liraglutide patent and it was decided to discontinue Victoza from December 2024. The first wave of liraglutide biosimilar products have been approved in the UK and this will help support the increasing demand for GLP-1 RAs and provide patient choice. Some patients prefer the once daily GLP-1 RAs to the once weekly due to tolerability. Numbers of patients are small and BLMK currently has 130 patients on Victoza. There are currently two biosimilars on the market and it is expected that this number will increase. The presentation of the new pens is like Victoza which would prevent patient confusion. Zegluxen® is the most cost-effective choice currently being 35% cheaper than Victoza and 19% cheaper than the other UK licensed biosimilar. The proposal, therefore, is to add the Zegluxen® biosimilar to the formularies as green. It is not in the drug tariff yet, but the discontinuation of Victoza necessitates the need to add an alternative to the formularies.  The committee agreed to add Zegluxen®, a liraglutide biosimilar, to the formulary as green. |
| 5.5 | **Xonvea**  Xonvea® is an enteric coated tablet containing the antihistamine doxylamine (10mg) and the prodrug of Vitamin B6, pyridoxine (10mg). It is the only UK licensed product for treating nausea and vomiting in pregnancy (NVP) and was launched in 2018. It has been on the Canadian market since 1979 and in the US since 2013. Xonvea is the only medication specifically listed on our local formularies under vomiting in pregnancy, as Red.  Antenatal Care NG201 was published in 2021, and it doesn’t recommend Xonvea stating that the evidence is very old and of low quality and did not show a convincing effect on symptom improvement. However, NICE CKS for nausea and vomiting in pregnancy was updated in February 2024 to include recommendations from the Royal College of Obstetricians and Gynaecologists (RCOG) update to their Green-top Guideline No.69, Management of Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum. This states that there are safety and efficacy data for first line antiemetics such as anti (H1) histamines, phenothiazines and doxylamine/pyridoxine (Xonvea®) and they should be prescribed initially when required for NVP and Hyperemesis Gravidarum (HG). [Grade A] There are large amounts of safety data for doxylamine/pyridoxine and the antihistamines in general have fewer adverse effects than ondansetron. Because there are no clear data supporting increased efficacy of one class of antiemetic over others the suggested step wise approach is based predominantly on safety data. The CKS states that some women will require a combination of 3 or more antiemetics to control their symptoms.  RCOG lists Xonvea as a first line option along with cyclizine, prochlorperazine, promethazine and chlorpromazine. Xonvea® has been shown to have a small but statistically significant improvement in the mean Pregnancy Unique Quantification of Emesis (PUQE) symptom score (a measure of the severity of nausea and vomiting). The UK Teratology Information Service (UKTIS) state that no additional foetal monitoring is required for mothers taking this combination. The FDA has given doxylamine/pyridoxine a Pregnancy Category A status – highlighting no risk in human studies or foetus during the first trimester.  However, Xonvea is a cost pressure, and we are estimating that if 661 women (half the number of women predicted to experience severe nausea and vomiting in pregnancy annually in BLMK) were treated for 12 weeks this would be a potential local cost of over £300,000.  The SMC and AWMSG decided not to recommend Xonvea’s use within NHS Scotland and Wales based on insufficient information on clinical superiority or cost effectiveness in comparison with recognised treatments for NVP in turn recommending the treatment cascade to follow the guidance outlined by the Royal College of Obstetricians and Gynaecologists (RCOG) – this was before the update in 2024.  Cambridgeshire and Peterborough have it on their formulary for specialists to initiate and if benefit is shown, primary care clinicians may continue treatment in the community. The Pan Mersey Area Prescribing Committee list it as green. Other areas within the East of England region do not have formulary decision on the use of Xonvea.  Given this information, the group were asked to consider reviewing the current formulary designation of Xonvea from red to allow prescribing within primary care.  The group discussed that costs could be saved from preventing admissions for hyperemesis and the need to be given IV fluids due to dehydration. Although Xonvea is listed as first line by RCOG, it needs to be taken regularly and there are several alternative first line, as required, options included too. It was suggested that women are given more supportive advice to prevent the need to be admitted (this is also detailed in the NICE CKS). A lack of familiarity with the medication and use in combination (as suggested in the guidance) leading to potential adverse effects meant that the GPs were more inclined towards the specialist advising before taking over prescribing.  BHFT have considered Xonvea twice at DTC and it was approved for use on the proviso of completion of an audit. There would be value in understanding local experience and outcome from this audit.  FG suggested a decision is delayed until BHFT have the audit data, and it is presented to FSG by BHFT. FG asked that BHFT also consider its formulary designation in their review. |
| 5.6 | **Progesterone pessaries for HRT**  JCu is a GP, and a British Menopause Society approved menopause specialist and trainer, she runs the Milton Keynes Hospital menopause clinics alongside the gynaecology consultants and works privately.  Endometrial protection in the form of progesterone is required for women with a womb/endometriosis who are on HRT via a variety of licensed options such as oral body identical (micronised progesterone), oral synthetic, transdermal synthetic and IUS (Mirena coil). However, a minority of women struggle with severe side effects (bloating, breast tenderness, drowsiness, fatigue, and the greatest issue tends to be mood disturbance) to a variety of products and they are classed as “progesterone intolerant”. For these women the remaining option is vaginal administration of progesterone. This is included in guidance from the British Menopause Society although there isn’t a lot of study data and there is uncertainty around dosing. With this administration, absorption is local, it avoids first pass metabolism and there are fewer side effects.  The first line option is the use of oral 100mg micronised progesterone inserted vaginally. 100mg daily for those on continuous HRT and two, 100mg capsules for 12 days for those on sequential HRT.  The second line option would be Cyclogest 200mg pessaries, one on alternate days or half daily (sliced lengthways with a scalpel or razor) for continuous regimes or one daily for 12 days for sequential regimes.  The flexibility in dosing depending on the woman’s regime cannot be achieved with the 200mg vaginal capsule (NB: licensed for Assisted Reproductive Technology (ART) and prevention of preterm birth, not for HRT).  There are a very small number of women that have been unable to tolerate micronised progesterone intravaginally and have subsequently done better on Cyclogest e.g. a woman who felt so drowsy she couldn’t drive the next day and another woman who felt suicidal. Cyclogest may also be preferred to micronised progesterone for religious or dietary reasons as it doesn’t contain gelatine.  As Cyclogest is currently red on the formularies, patients needing this despite having tried the alternatives would need a referral and potentially long-term prescriptions from secondary care.  The proposal therefore is to change Cyclogest from red to amber under specialist recommendation only.  It should be noted that the vaginal micronised progesterone (Utrogestan) and Cyclogest are not licensed for HRT. The oral capsules are green on the formulary but that is for the oral licensed use and a differentiation would need to be made for use of the oral capsule vaginally as SpIS to make it clear that it is a specialist in HRT (i.e. a Consultant Endocrinologist/Gynaecologist or a primary care clinician who has relevant experience and is clinically competent to prescribe) initiating and stabilisation.  It was agreed that Cyclogest pessaries are added to the formulary as SpIS for off-label HRT use where micronised progesterone oral, used vaginally, has not been tolerated. |
| 5.7 | **Colecalciferol 3000 units/ml liquid** – deferred to next meeting |
| 5.8 | **Omalizumab biosimilar**  This is a formulary amendment to add an omalizumab biosimilar (Omlyclo®) to the formularies. The originator brand (Xolair®) is indicated for severe persistent allergic asthma, NICE TA278 (NHSE commissioned) and previously treated chronic spontaneous urticaria, NICE TA339 (ICB commissioned). A national procurement process has been undertaken to make Omlyclo available for use in the NHS. The framework start date was September 2024 and availability is anticipated by Q1 2025. It is available as 75mg and 150mg pre-filled syringes (Xolair® available as 75mg, 150mg and 300mg PFS and PFP (currently no local use of 300mg and PFP)). This will result in approximate 42% price reduction per dose.  It was agreed to add Omlyclo, an omalizumab biosimilar to the formularies as red. |
| 5.9 | **Calcium and Vitamin D formulary alignment**  NICE CKS for osteoporosis recommends prescription of calcium and vitamin D depending on calcium intake and low vitamin D risk factors such as being house bound or in a nursing home (800IU daily).  These preparations have been brought to the subgroup to align choices across the formularies and steer prescribers to the more cost-effective options that are likely to be better tolerated to aid compliance.  The first line options are the once daily preparations that should aid compliance and include Calci-D, Accrete D3 One a day and TheiCal-D3. These products are suitable for vegetarians and those with allergies to peanuts, soya or soya bean. Second line options, if a patient prefers a non-chewable tablet include Accrete D3 and Adcal D3. Effervescent options include ColeKal-D3 Dissolve and Cacit D3 Dissolve (recommended by NEWT for those patients being tube fed). Accrete D3 non-chewable and Cacit D3 effervescent are the only products not suitable for vegetarians or patients with an allergy to peanuts, soya or soya bean.  Formulary entries for the effervescent preparations will state the quantity of sodium.  No active bulk switching of products is being recommended, but these are the preferred options for new initiations.  The hospitals have stated that patients will be supplied with the brands dictated by their contract pricing and availability so the statement regarding ‘hospital contract brands will be supplied in secondary care’ will be retained on the formularies. If patients are switched when admitted, primary care request for the reason to be stated e.g. if clinical or based on availability.  The group agreed to the recommended calcium and vitamin D products for formulary alignment. |
| 5.10 | **Budenofalk® suppositories**  Lianne Lewis is an inflammatory bowel disease nurse at MKUH, and this application has been brough by the gastro team at MKUH.  This is a request for the inclusion of budesonide 4mg suppositories to the formularies for mild to moderate ulcerative proctitis, which affects 30-50% of ulcerative colitis patients. Early initiation can prevent deterioration and the risk of disease progression. Budesonide suppositories topically target rectal inflammation and are better tolerated then prednisolone by patients with low systemic absorption. The dose is 4mg once daily for 6-8 weeks. Studies show that those patients not responding to mesalazine have a mucosal and symptomatic response to budesonide. The current option available on the formulary is prednisolone 5mg suppositories. There are no comparison studies, but prednisolone suppositories cost significantly more. If 20% of patients currently on prednisolone were initiated on budesonide, this could save over £28,000 annually. Budesonide suppositories are being requested as an additional option to existing treatments for patients to help in the (self) management of their chronic condition. MKUH use a patient portal called Iona, and budesonide will be built into it to support patients if approved.  Budesonide 4mg suppositories were approved for addition onto the formularies as SpA. |
| 5.11 | **JAC merger and formulary alignment**  This is a standing agenda item for documentation and governance of formulary alignment in line with work around JAC merger at BHFT.  The group approved the recommendations made from this review, which include:   * Promazine is non-formulary on BLF and formulary in MKF, it was agreed by CNWL and MKUH to align with BLF. * Fenofibrate 160mg tablet is used by lipid clinics for people with raised triglycerides and in patients with conditions such as familial hypercholesterolaemia. The group agreed to designate as green to allow primary care clinicians to initiate. * After consultation with hospital colleagues, it was agreed that GTN patches should be designated red on the formulary as use was mainly by specialists e.g. for patients receiving parenteral nutrition via peripheral veins and use at BHFT, as vascular specialists, for vascular and cardiology patients. |
| 6 | **Minor amendments log**  Noted. |
| AOB | **Blood glucose and ketone testing**  The table for the preferred blood glucose and ketone meters has been updated on the formularies with the corresponding test strips.  **Fluoride toothpaste on prescription**  Norfolk and Waveney have information on their website stating that these fluoride products are self-care items that should preferentially be prescribed by a dentist. However, patients that have had head and neck cancers are advised by oncologists to use high fluoride toothpaste long term. In this situation, it is recommended that the specialist act as the dental service and issue prescriptions.  Our current Optimise Rx message advises that as GPs aren't the specialists in dental care, they shouldn't be prescribing.  Discussions at MKUH with ENT and head and neck consultants in the past has raised concerns that patients unable to access dental services would be unable to obtain treatment.  Prescribing of high fluoride toothpaste does require review and there is a risk it is left on a patient’s repeat without this. If the family is having issues with dental access, they may share the toothpaste with the risk of fluorosis in children.  BLF lists high fluoride toothpaste as red and MKF as non-formulary.  The committee agreed to designate high fluoride toothpaste as red and for the other fluoride products, that are available OTC, non-formulary. BMA recommendations for GP dental prescribing will be linked to the formulary entry. |
|  | Meeting dates for 2025 are available on BLMK ICB Website – Formulary Page  <https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/> |

Chair Signature: 

Date: 14.05.2025