Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday January 9th, 2024, 12:00-14:00
via MS Teams

Name	Title	Organisation	Aug	Sep	Oct	Nov	Dec	Jan
Dr Peter Budden (PB) Chair	Medical Prescribing lead	NHS GMIC (Salford)	✓	A	✓	✓	✓	✓
Dr Jonathan Schofield (JS)	Consultant Physician Acute Medicine & Diabetes	Manchester FT	✓	✓	✓	✓	A	A
Suzanne Schneider (SS)	Medicines Information Pharmacist	Bolton FT	✓	✓	✓	✓	✓	✓
Gary Masterman (GM)	Associate Director of Pharmacy	Wrightington, Wigan and Leigh FT	A	✓	✓	✓	A	A
Andrea Marrosu (AM)	High-cost Medicines and Home Care Pharmacist	Salford Royal FT	✓	A	✓	✓	✓	A
Peter Marks (PM)	LPC Board Member	GM LPC		✓	✓	✓	✓	✓
Mina Chowdhury (MC)	Medicines Optimisation Pharmacist	NHS GM IC (Heywood, Middleton & Rochdale)	✓	✓	✓	✓	✓	A
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	NHS GM IC (Bury)	JSe	✓	JSe	✓	✓	✓
Matthew Ling (MB)	Deputy Director of Pharmacy	GM Mental Health FT	SB	✓	✓	✓ & SB	✓	✓
Faduma Abukar (FA)	Head of Medicines Management	NHS GM IC (Stockport)	JC	JC	JC	A	A	A
Zoe Trumper (ZT)	Assistant Director of Medicines Management	NHS GM IC (Wigan)	A	✓	✓	✓	✓	✓
Sarah Hafeez (SH)	Advanced Medicines Optimisation Pharmacist	NHS GM IC (Tameside)	FB	FB	FB	FB	FB	✓
Jennifer Bartlett (JB)	Team Leader Neighbourhood Integrated Practice Pharmacists	Salford Royal FT	✓	A	✓	✓	✓	✓
Claire Foster (CF)	Senior Medicines Optimisation Adviser	NHS GM IC (Manchester)	✓	✓	✓	✓	✓	A
Jole Hannan (JH)	Interface Pharmacist	NHS GM IC (Bolton)	A	✓	✓	✓	✓	✓
Leigh Lord (LL)	Head of Medicines Optimisation and Governance	Manchester FT	SBo	✓	✓	✓ & LK	✓	✓
Consultant Rheumatologist Audrey Low Charlie Filer Dipak Roy Louise Mercer Sahena Haque Anindita Paul		SRFT Stockport TGH Stockport UHSM Bolton	A	A	A	A	AL	A
Dan Newsome (DN)	Principal Pharmacist	RDTC	✓	✓	✓	✓	✓	✓
Nancy Kane (NK)	Senior Medical Information Scientist	RDTC	✓	✓	✓	✓	✓	✓

Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	NHS GM IC	✓	✓	✓	✓	✓	✓
Karina Osowska (KO)	Medicines Optimisation Pharmacist	NHS GM IC	✓	✓	✓	✓	✓	✓

1. General Business	
1.1	**Welcome and apologies** Apologies as noted above, the meeting was quorate. Anna Pracz and Dr Adam Zermansky were in attendance for item 4.1
1.2	**Declarations of interest** Previously declared where relevant. No further declarations made at the start of the meeting
1.3	**Draft December 2023 CRG Minutes** The minutes were approved for publication to the GMMMG website Two matters arising from the minutes were discussed. Cytisine as a smoking cessation aid is available to purchase as a herbal product (Tabex) but the licensed product for which a formulary application has been received is a POM and therefore PGDs will be required for supply. CRG heard that these are being developed by the relevant services. Tadalafil 5mg daily tablets were removed from the DNP list but subsequent correspondence has demonstrated there is a need to amend the formulary to show PDE-5 inhibitors are not recommended for use in LUTs as per CG97. A clause in the SLS section of the drug tariff does in fact permit the use of this class of medicine for conditions other than erectile dysfunction so clarification is required for primary care prescribers and will be discussed at a subsequent CRG meeting.
1.4	**Action log review** The owner of each action will be approached for updates if not already provided to CRG. Some items have full agenda items. Others have progress as follows: • Buvidal: Application still pending but both the local service in Wigan and the GM service leads have been approached for this now. • Steroid eye drops prescriber information: This will now be scheduled for the Feb 24 meeting at which a MREH clinician will attend to discuss • Tirzepatide: positioning of this treatment within the T2DM pathway has been requested from the GM diabetes strategy board. No response received to date • Promethazine tablets: discussions within mental health services are ongoing, and an update will be provided to Feb CRG by ML/SB
2.0 Matters arising	
2.1	**CRG Consultation November 2023** The comments received through the consultation were discussed, including following items: **Acetylcysteine 500mg effervescent tablets:** comments from specialist clinicians showed some support for this change but one questioned the evidence base for the recommendation. There are a number of metanalyses which do show a small but significant reduction in exacerbations associated with the use of acetylcysteine in COPD and bronchiectasis. This evidence will be forwarded to the commenter and the formulary amendment will be recommended to GMMMG. **Rimegepant for treating Migraine (TA919):** Dr Adam Zermansky as head of the GM headache service at SRH attended to discuss the placement of this agent and it was agreed that it should be Green for the treatment of acute migraine as this is something that is managed in primary care and provides a safe and effective treatment option if triptans and other simple analgesia are ineffective (in line with NICE TA recommendations). **Daridorexant for treating long-term insomnia (TA922):** Comments received suggest that primary care prescribers and MO teams do not think this is a useful addition to the formulary and that there is a

	requirement for a pathway to be developed to support its use for those in those for whom it is appropriate. CRG further discussed the issues with the evidence base and the receipt of a long-term license from the MHRA despite only having data for up to 12 months of use, the lack of consistent commissioned CBTi services and the exclusion of patients with a mental health condition from the trials despite these making up a large proportion of the current cohort treated with benzodiazepines or z-drugs for insomnia, often used long term despite the risks associated with this. It was suggested that some of this cohort may be transferred to the only product with a long-term use license and could therefore increase the already significant cost impact (£2m per year by year 5) for GM. It was mentioned that information has been received that NHSE are commissioning CBTi for all ICBs but there is currently no further detail. CRG were therefore unable to make a formulary recommendation at this stage where so many uncertainties exist. They agreed it is likely appropriate for primary care prescribing and this is where NICE have positioned it but the pathway is key, which in turn depends on the scale and availability of the commissioned CBTi services, a question which CRG are unable to answer. Therefore these issues will be escalated to GMMMG to ask for resource to create a primary care sleep pathway and for further information about CBTi commissioning. Should these be in place it would not be unreasonable to have a Green RAG status. **All other actions proposed were approved.** **Action**: RDTC to submit actions to GMMMG for approval and/or discussion.
3.0 Formulary and RAG	
3.1	**Formulary Amendments December 2023** CRG approved the formulary amendments to open for consultation and noted the following: • **TA29: Empagliflozin for treating chronic CKD:** There remains a significant cost impact associated with this despite it being the second NICE approved drug for this indication (dapagliflozin approved in March 2022). • **TA943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes:** The implementation of this guidance will be referred to the GM diabetes strategy board, noting the 5 year implementation period that NICE has advised. It was also noted that FreeStyle Libre 3 (FSL3) has been added to the drug tariff in January 2023. FSL3 is designed to work as part of the HCL systems and should not routinely be prescribed in primary care. CRG agreed that this should have a RED RAG status to avoid any confusion and will be included in this month's consultation. The adoption of NICE guidance on the use of CGM remains with the ICB executive committee which has requested details on the current usage of all CGM prior to making a decision. **Action: RDTC to open formulary amendments for GMMMG consultation**
3.2	**Benilexa formulary application** A request to add Benilexa, a one-handed levonorgestrel (LNG) Intrauterine System (IUS) which delivers 20mcg/24hrs, was considered by CRG for its licensed indications of contraception (up to 6 years of treatment) and heavy menstrual bleeding. It was also requested for off-label use as part of HRT which is supported by guidance from the FSRH. CRG heard it is pharmacologically identical to Levosert which is on the formulary and licensed for the same indications, but Benilexa is marketed at a slightly higher price and has a larger insertion tube which may make it unsuitable for some patients. It has advantages over Mirena and Kyleena in terms of cost but CRG agreed it was sufficiently different to warrant adding as a further option alongside the current formulary choices. CRG noted the recent license extension of Mirena for 8 years for contraception which would now make it the cheapest for this indication alongside Levosert. **Decision:** CRG agreed Benilexa should be a treatment option in addition to the existing products on the formulary including off-label for HRT and will be included in the consultation.
3.3	**Melatonin 1mg/mL SF oral solution – Consilient and Ceyesto products formulary application**

	A comprehensive submission requesting the addition of licensed products of melatonin 1mg/mL SF to the formulary was received. It requests that the Consilient and Ceyesto products should be placed as preferred liquid products for children in line with the current GM shared care protocol when solid dosage forms are not appropriate. The use of liquid preparations should be limited to exceptional circumstances as defined in the SCP yet there is around £3.4m of prescribing of melatonin liquids being done in GM per year, therefore CRG recognised the key piece of work is to promote the use of Adaflex tablets which are licensed for crushing and also supporting patients to swallow tablets. However the work undertaken by Oldham MO team has shown that considerable prescribing of generic melatonin 1mg/mL SF happens in GM and patients could be receiving the Colonis brand. This was added to the DNP list due to its propylene glycol content and the associated safety risks as defined by the EMA and NPPG. Up to 359 patients could be receiving the Colonis product despite a recommendation that the prescription is issued as “propylene glycol free”. This constitutes a safety issue that requires addressing. The proposal was therefore to add the Consilient brand as first line liquid option for patients aged 5 years or under due to its lack of propylene glycol. This would be cost neutral (provided the Drug Tariff price for melatonin 1mg/mL SF remains relatively constant). It also requested that Ceyesto would be the preferred liquid product for patients aged 6 years and over as it contains only small amounts of propylene glycol and benzoyl alcohol but well below the recommended safe thresholds. This would be cost-saving by up to £347k per year for GM. A total switch is not advocated, but as appropriate patients who are prescribed an unlicensed product should be reviewed and with the intention to change to a solid dosage form (crushed if necessary), however if it is determined a liquid product is essential then a change to a licensed formulary choice would be recommended. The shared care protocol will need to be amended to support this formulary change once it is approved through GMMMG governance process. **Decision:** Open a GM-wide consultation based on the request above.
4.0 Pathways and Clinical Guidelines	
4.1	**Rimegepant – RAG review and factsheet** The group discussed both the RAG recommendations for TA919: Rimegepant for treating migraine as well as TA906: Rimegepant for preventing migraine which has already been added to the formulary as a Green specialist initiation medicine. Dr Adam Zermansky as the Clinical lead for the GM headache service based at SRH attended to discuss and present the case for making the medicines Green specialist advice for prevention of episodic migraine and Green for treatment of acute migraine. Dr Zermanksy reasoned that rimegepant is a safe and effective medicine and the majority of patients with both conditions are managed in primary care. There are logistical issues associated with asking patients to obtain the medicine from secondary care, who have no facility to prescribe remotely necessitating trips to Salford, as the sole service provider, on at least 2 occasions to obtain the medicine. Blueteq forms collected at SRH show that 90% of migraine therapy prescribed is for the chronic condition and not episodic, showing the service’s focus on the chronic condition and the lack of capacity to accept patients with episodic migraine. The headache service would therefore prefer to accept advice and guidance requests from primary care regarding the initiation of rimegepant for prevention of episodic migraine and the 12 week review of efficacy could reasonably be undertaken in primary care. A document has been produced to facilitate a GP, nurse practitioner, or pharmacist to undertake this. CRG were concerned about the potential for a cohort of patients currently receiving injectable treatment for preventative conditions being transferred to rimegepant and increasing the numbers receiving the medicine in primary care. Assurance was received that only a small number of patients would be suitable for this change in therapy. **Decision:** Pending some minor amendments to the rimegepant factsheet, this was approved to open for consultation

	Rimegepant for treatment of migraine (in line with TA919) will be recommended to GMMMG for addition to the formulary with a Green RAG status Rimegepant for prevention of migraine (in line with TA906) will open for consultation to change the RAG status from Green specialist initiation proposed to Green specialist advice.
4.2	**Steroid eye drops – discussion with specialist service** Deferred until February 2024 meeting
4.3	**Omalizumab for CindU – Blueteq forms** CRG approved the Blueteq forms for use by the two services using omalizumab for chronic inducible urticaria in line with the recently approved commissioning statement. CRG recognised there is little expertise on the group regarding Blueteq forms but that the documents were developed by those who will use them and that in future these may be able to be approved by a HCDs subgroup of GMMMG which is being developed. **Decision** Approved for system-wide use
5.0 Shared care	
6.0 Work plan and horizon scanning	
6.1	**Monthly horizon scanning December 2023** CRG considered the contents of the document and made the following comments. • A biosimilar of tocilizumab has been licensed in the UK – price as yet unavailable but this is a relatively low spend HCD. Capacity to make switches to biosimilar ustekinumab which is also expected during 2024 should be a priority • Tirzepatide has received a license as expected for its weight loss indication. A NICE TA is anticipated for publication in March 2024
7.0 AOB • LL raised the issue of local vs system-wide working for the development of formulary applications, guidance and pathways. CRG agreed that the group would facilitate discussions about how best to manage these as they arise, to share work and to find expertise across the system who can contribute to the development of ICS-wide guidance.	
Date of next meeting: Tuesday 13th February 2024 12:00-14:00 via Teams	