Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday June 14th 2022, 12:00-14:00
via MS Teams

Name	Title	Organisation	Dec	Feb	Mar	Apr	May	June
Dr Peter Budden (PB) Chair	GP	St Andrews Medical Practice				✓	✓	✓
Dr Helen Burgess (HB)	GP	Manchester Health and Care Commissioning				✓	A	✓
Dr Jonathan Schofield(JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓	✓	✓	✓	A
Sarah Boulger (SBo)	Medicines Information Pharmacist	Pennine Acute	A	✓	✓	A	A	A
Suzanne Schneider (SS)	Medicines Information Pharmacist	Bolton FT	✓	✓	✓	A	✓	✓
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	A	A	A	A	A	A
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	✓	✓	✓	A	A	A (MC)
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	✓	✓	SM	✓	A
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	A	✓	A	A	A	A
Faduma Abukar (FA)	Head of medicines management	Stockport CCG	A	✓	A	✓	✓	✓
Zoe Trumper (ZT)	Assistant director of medicines management	Wigan Borough CCG	A	✓	✓	A	✓	✓
Faisal Bokhari (FB)	Deputy Head of Medicines Optimisation	Tameside & Glossop CCG	✓	A	✓	✓	A	✓
Jennifer Bartlett (JB)	Team Leader Neighborhood Integrated Practice Pharmacists	Salford Royal FT	✓	A	✓	✓	✓	✓
Claire Foster (CF)	Senior Medicines Optimisation Adviser	Manchester Health and Care Commissioning	✓ AH	✓	✓	✓	A (AH)	✓
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG	✓	✓	✓	✓	✓	✓
Jacqueline Coleman (JC)	Medicines Optimisation, Interface Pharmacist	Stockport CCG			✓	A	A	A
Charlotte Atkinson	Specialist Pharmacist	Manchester FT						✓
Consultant Rheumatologist Audrey Low		SRFT	✓ DR	A	✓ AL	✓ AP	A	✓ DR

Ben Parker Charlie Flier Dipak Roy Louise Mercer Meghna Jani Sahena Haque Anindita Paul		MFT Stockport TGH Stockport SRFT UHSM Bolton						
Dan Newsome (DN)	Principal Pharmacist	RDTC	✓	✓	A	✓	✓	✓
Nancy Kane (NK)	Senior medical information scientist	RDTC	A	A	A	✓	✓	✓
Conor McCahill (CM)	Senior Pharmacist	RDTC	✓	✓	✓	✓	✓	✓
Andrew White (AW)	Head of Medicines Optimisation	JCT	✓	✓	✓	✓	✓	A
Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	JCT	✓	✓	✓	✓	✓	✓
Karina Osowska (KO)	Medicines Optimisation Pharmacist	JCT	A	✓	A	A	A	✓

1. General Business	
1.1	**Welcome and apologies** The chair welcomed the group and noted apologies as above. Mina Chowdhury and Charlotte Atkinson also joined the group.
1.2	**Declarations of interest** Previously declared where relevant. No new declarations of interest were disclosed.
1.3	**Draft May 2022 CRG Minutes** The May 2022 CRG Minutes were accepted.
1.4	**Action log review** Most items had no updates, the action owners will be approached for updates. **1. 08215.2 SCP for melatonin in children and adolescents** It was noted that there is an aim to include new product (Adaflex®), and this update is now in progress and it will come to CRG with appropriate formulary documentation **2. 02223.3 Dacepton (apomorphine) – addition to shared care protocol** It was highlighted to the group that there is a pending request for consideration of moving the RAG status from Amber to Green Specialist Initiation, and it was suggested this be discussed at the July 2022 CRG meeting as the SCP update may no longer be required. . **3. 02223.4 Actinic Keratosis pathway review; Tirbanibulin to be considered within pathway review** KO updated the group that this pathway is on hold due to limited capacity at present and will resume once the HRT guidance is finished.

	4. 042204 Modafinil information leaflet AM advised the group that this is currently on the priority list with the aim of bringing to the July 2022 CRG meeting.
1.5	**Update from GMMMG** No update provided. GMMMG did not meet in June
2.0 Matters arising	
2.1	**CRG Consultation April 2022** Comments were acknowledged by the group, and the decision made to send the contents to GMMMG for approval. **Action**: RDTC to submit actions to GMMMG for approval.
3.0 Formulary and RAG	
3.1	**Formulary Amendments May 2022** CRG approved the formulary amendments to open for consultation and noted the following: **1.** TA791 – Romosozumab for treating severe osteoporosis It was noted that as this is a secondary care drug, there is likely going to be agreement for this to remain as a Red drug in the RAG list. It was also noted that no comments have been received from Rheumatology prior to CRG. Concerns regarding Blueteq processes and possible delays were highlighted. It was asked if there is an alternative option to Blueteq, though it was clarified that at present there are no other options. DR noted that the NICE TA appears to suggest this can be used first-line, as it doesn't require failure of other agents. This differs to the status of teriparatide, which would now be considered at a similar position in the NOGG guidance pathway to Romosozumab. It was noted that the NICE TA which covers teriparatide (NICE TA161) has not been update since the marketing of biosimilar agents, and still places teriparatide after bisphosphonates. The NICE threshold for use of romosozumab (e.g., no requirement for T-scores) may mean GM see a large number of eligible patients for treatment. DR also confirmed that an initial assessment would estimate many more patients than the NICE TA suggests, especially as no baseline requirements, he stated the rheumatology team would like this option to exist for teriparatide, too, which may offset some of the increased costs to the system by implementing this TA. There was a suggestion, in line with above, that referring to the NOGG guidance and a statement to encourage the more cost-effective treatment option would be appropriate. CRG agreed to open this for consultation as a first line anabolic treatment alongside teriparatide. **Epiduo gel (adapalene / benzoyl peroxide)**

	This is proposed as a technical update to add Epiduo 0.3/2.5% to the formulary alongside the lower strength product, which is currently listed. However, it was discussed that instead it should be amended to remove product information and leave as "Epiduo", to cover both strengths. **2. Topical vitamin D / steroid preparations for psoriasis** A request was made to amend the GMMMG formulary to align with the GM guidelines for the management of psoriasis by removing the brand name from betamethasone/calcipotriol products and inserting a statement that that prescribers should choose the most cost-effective option. **3. Macrogol products on formulary** Macrogol 3350 listed as first choice, however the most cost effective options are likely to be alternative macrogol products e.g. macrogol compound NPF. Therefore the restriction to macrogol 3350 has been removed and a note for prescribers to use the most cost effective option inserted. **4. Minoxidil preparations** This is a technical update to clarify the status of minoxidil foam which is listed in the GMMMG formulary as "Not presribeable on the NHS" which is not strictly correct as it is not listed in part XVIIIA (blacklist) when other minoxidil products are. CRG agreed to give minoxidil foam a DNP status (criterion 3) and assign wording to the remaining minoxidil product to show these will not be reimbursed as per part XVIIIA of the drug tariff. **5.** MTG70: Sleepio to treat insomnia and insomnia symptoms It was noted that whilst links to technologies are not usually included in the formulary, this may be applicable to those with insomnia who may otherwise use drugs of potential abuse. It was decided to leave the formulary as medicines-focused, but to include links to guidance when felt to be appropriate. **Action:** RDTC to open formulary amendments for GMMMG consultation
3.2	**Utrogestan for preventing miscarriage – RAG Status** This item was previously discussed, and consultation began in December 2021. In March 2022, CRG was asked to approve a Red RAG status. Specialist opinion was sought, and there are differing views as to whether Red or Green following specialist initiation would be the most appropriate way to manage prescribing It was noted that making the medicine Green following specialist initiation would mean specialist input is required at the start as recommended under NICE guidance, but should lead to fewer situations in which patients struggle to get ongoing supplies of medication. It was asked whether patients have regular follow-ups with specialist (in which case, Red wouldn't be a barrier to prescriptions), and it was clarified that patients sometimes do not have specialist follow-ups within the timescale required for subsequent prescribing. It was also highlighted that Green with specialist initiation would not prevent specialists from keeping prescribing in the specialist service if they felt to be most appropriate. **Decision**: Utrogestan to be Green with Specialist Initiation for this indication

3.3	**Lixisenatide – Discontinuation of 10microgram & Initiation Pack** Sanofi have discontinued both of these products, meaning new patients cannot start treatment. It was noted that if patients cannot start lixisenatide, then it seems illogical to retain it on the formulary at higher strengths (for maintenance treatment). It was suggested (and agreed by the group) that the item is removed from the formulary, with a note added to clarify existing patients can continue as long as they are able to, if appropriate to do so. **Decision:** Lixisenatide to be removed from formulary, with guidance note to explain the reason and that patients established and stable on treatment can continue whilst products are available.
4.0 Pathways and Clinical Guidelines	
4.1	**DOAC choice for AF & implications of Teva/Sandoz vs Apixaban ruling** The edoxaban framework has previously been discussed at CRG, and it was noted there is an IIF indicator for primary care to encourage edoxaban use. There have been amendments to the DOAC choice document since the last time it was discussed at CRG, and it now reads that edoxaban should be first line unless there is a compelling reason not to do so. The intention was to open for GM-wide consultation if not for the recent court ruling (Teva/Sandoz vs.BMS) which has invalidated the BMS Eliquis® patent. It was emphasised that there is still the opportunity for BMS to appeal this decision. As its stands there is generic apixaban in the market but insufficient to cover the amount of branded apixaban being prescribed and current at the same price for primary care. Apixaban is listed within the Drug Tariff as a Category C medication, meaning generics would still be reimbursed the price for Eliquis® for the foreseeable future, and there would be no savings to be anticipated in the short-term. However, generic items should enter the Tariff from September 2022, and this should drive costs down. Areas of concern included whether it is appropriate to swap patients to edoxaban and then back to apixaban in several months' time, and whether it is better to hold off on making a decision, knowing that IIF indicators require an increase in edoxaban use now. It was noted that when this issue was previously discussed with CCG MO lead representation, there was a suggestion that the GMMMG work is paused temporarily whilst awaiting clarification on the situation as at present there is not likely to be a "right" decision. It was broadly agreed that edoxaban should be the first-line option for now, regardless of ongoing legal case(s), for patients requiring treatment initiation and for patients suitable to convert to a DOAC from a VKA. This would be the case unless there were clear clinical reasons it would be unsuitable. (See below.) There was discussion regarding the appropriateness of swapping from other DOACs to edoxaban at the current time, and broadly agreed that swapping from rivaroxaban and dabigatran to edoxaban may be appropriate, but that there should perhaps be a hold on apixaban changes until there is clarity as to the situation with apixaban generics. CRG agreed that any switch programmes should be for local decision and declined to advocate for this practice.

	It was suggested that the current phrasing in the document of "compelling reason" to choose a DOAC other than edoxaban is open to interpretation, and there may be those who prefer to prescribe alternative DOACs because they perceive them as being better for certain conditions, in the absence of direct comparative studies. It was also noted that the current language is vague in parts and isn't clear as to what action should be taken, and it was confirmed that this is because there isn't a great deal of good evidence for many of the recommendations. Therefore, it was suggested that choice should be based on cautions and contraindications and should be safe. I was stated this would clarify the position that edoxaban is the first-choice option unless there was a clinical reason (rather than clinician preference) to start another DOAC. It was noted that the original purpose of the documentation is now perhaps undermined by the ongoing legal case(s), and if that because of complex patient groups (I.e., patients may have more than one comorbidity) the choice of DOAC becomes harder, and it may be simpler to remove the clinical factors and advise edoxaban as first-line unless a contraindication or significant caution exists Decision: PB and DN discuss this outside of CRG, and draft a statement for comment by members prior to a consultation.
4.2	**Hypersalivation Pathway** It was discussed that hypersalivation medications were previously at CRG for RAG status changes, and a pathway update was requested. The RDTC has proposed minor edits (re-ordering product choices based on cost where otherwise equal, and adding "tablets and patches" to "hyoscine hydrobromide" in appendix 1). **Action:** Approved to open for consultation.
4.3	**HRT Resources – Shortages and alternatives** At the May 2022 CRG meeting, HRT product shortages were noted as an ongoing problem. The addition of links to the BMS and SPS websites, which are kept up-to-date, will help with queries regarding this. **Action:** Add the proposed links to these resources to the formulary.
5.0 Shared care	
5.1	**GnRH analogues for breast cancer** This item has been out for consultation, and comments have been received and, where relevant, acted upon by the authors. It was noted that there is a possible increased workload for GPs if they are responsible for arranging DEXA scans, and that this is included in "ongoing monitoring". It was suggested that further clarification could be provided within the document regarding responsibility for requesting a scan. **Decision: Approved to go to GMMMG for ratification**
6.0 Work plan and horizon scanning	

6.1	**Horizon scanning May 2022** CRG noted the contents of the document, and one item was discussed. **1. New Product: Melatonin 1mg, 2mg, 3mg, 4mg, and 5mg tablets (Adaflex®, AGB-Pharma AB)** This new licensed formulation of melatonin for children was highlighted, as this may mean a move away from crushing other melatonin tablet products, and it seems to be reasonably priced. It was noted that the SCP is currently undergoing amendment to add this product, though also suggested that now there is a licensed melatonin product (for this indication) there may no longer be a requirement for a shared care protocol. The treatment pathway, particularly regarding transition from paediatric to adult services with melatonin treatment, was noted, and it was recommended these discussions could be had when the updated SCP returns to CRG.
6.2	**GMMMG (JCT) work plan** CRG was informed that the overarching work plan is in progress and will be finalised soon.
7.0 AOB **No other items were discussed**	
Date of next meeting: Tuesday 12th July 2022 12:00-14:00 via Teams	