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

Name	Title	Organisation	Feb	Mar	Apr	May	June	July
Dr Peter Budden (PB) Chair	GP	St Andrews Medical Practice			✓	✓	✓	✓
Dr Helen Burgess (HB)	GP	Manchester Health and Care Commissioning			✓	A	✓	A
Dr Jonathan Schofield(JS)	Consultant Physician Acute Medicine & Diabetes	Manchester FT	✓	✓	✓	✓	A	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	✓	A
Andrea Marrosu (AM)	High-cost Medicines and Home Care Pharmacist	Salford Royal FT	✓	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)	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	✓	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	✓	✓	✓	A (AH)	✓	✓
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG	✓	✓	✓	✓	✓	✓
Jacqueline Coleman (JC)	Medicines Optimisation, Interface Pharmacist	Stockport CCG		✓	A	A	A	A
Charlotte Atkinson	Specialist Pharmacist	Manchester FT					✓	A
Consultant Rheumatologist Audrey Low		SRFT	A	✓ AL	✓ AP	A	✓ DR	A

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	✓	✓	✓	✓
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. Jennifer Seal (NHS Greater Manchester ICB) also joined the group, as did Mina Chowdhury (NHS Heywood, Middleton and Rochdale CCG) in place of Keith Pearson. The group was not quorate for these discussions due to the absence of any representative from mental health.
1.2	**Declarations of interest** Previously declared where relevant. No new declarations of interest were disclosed.
1.3	**Draft June 2022 CRG Minutes** The June 2022 CRG Minutes were accepted as a true record. Two matters were discussed relating to the minutes. 1. **DOACs** The draft statement referred to in the minutes has now been opened for consultation. It was also noted that the reference product in the drug tariff is no longer Eliquis®, but is listed as generic apixaban at the same price. It was noted there are now generic TEVA and Sandoz apixaban SPCs on eMC, and both are in dm+d. The appeal has been launched and the outcome is being awaited before reconsideration is given to the planned switch to edoxaban. 2. **Romosozumab** It was noted there is a joint NOCC/Royal Osteoporosis Society statement that aids in identifying high-risk patients, which may help with interpretation and implementation of NICE guidance.

1.4	**Action log review** Most items had no updates, the action owners will be approached for updates. 1. **O2223.2 Steroid Eye Drops Review** Primary care teams have again noted concern with red status in the formulary for access, though CRG noted that it may aid in prompting reviews, as there is some concern this is not happening at present. It was noted that this item isn't progressing as was initially hoped, and the team is going to be approached. CF is going to pass contact details for a local MO pharmacist onto DN, to be involved in this work
1.5	**Update from GMMMG** No meeting in June, but there was a confirmation that items agreed at CRG previously will be taken forward.
2.0 Matters arising	
2.1	**CRG Consultation May 2022** Comments were acknowledged by the group, and the decision made to send the contents to GMMMG for approval. It was highlighted that comments were received about extra-medicinal support systems (i.e., outside of the remit of this group) for NG215 and NG217. These will be flagged to GMMMG when this is processed. **Action**: RDTC to submit actions to GMMMG for approval.
3.0 Formulary and RAG	
3.1	**Formulary Amendments June 2022** CRG approved the formulary amendments to open for consultation and noted the following: 1. **TA792 Filgotinib for treating moderately to severely active ulcerative colitis** It was noted that this is being included in the pending IBD pathway, so this will hopefully be back at CRG in August 2022. 2. **TA804 Teduglutide for treating short bowel syndrome** It was noted that as of April 2023, a number of specialist commissioned drugs will move to ICS commissioning, so this is included as RED in formulary to keep formulary up-to-date. 3. **NG219 Gout: diagnosis and management** It was noted that all medicines included here are on the formulary already, however the upper threshold for cost (£18,000 per 100,000 population in 2026/27) is above the threshold for CRG. The guidance recommends changes around blood tests and monitoring which were also noted as potential costs, however current practice may be unlikely to change as quickly as NCIE anticipate. 4. **NG222 Depression in adults: treatment and management**

	It was highlighted that antipsychotics are listed as augmentative treatment, with suggestion for primary care to manage under shared care protocols, which aligns with other disorders such as bipolar disorder. **5. Ranibizumab biosimilar granted marketing authorisation** The group action, to consider an amendment to formulary to position ranibizumab, was noted and discussed. It was highlighted that this is a vial, not a pre-filled syringe, though despite possible concerns with processes for uptake it was highlighted that as it is expected to reduce costs it should be positioned first-line. CRG noted that there is a working group under the Elective Care Reform Board looking at the introduction of the biosimilar. It was recommended that unless this group request otherwise CRG position biosimilar ranibizumab as first line product for its licensed-NICE approved indications. **Action:** RDTC to open formulary amendments for GMMMG consultation
3.2	**Adaflex formulary inclusion tool and RAG review of melatonin** This is a request for Adaflex®, a new, licensed formulation of melatonin for the treatment of insomnia in children and adolescents aged 6-17 years with ADHD where sleep hygiene measures were insufficient. It is also licensed for short term treatment of jet lag in adults, but this is not covered by this application. The request is to position Adaflex® as the first-line melatonin product for this indication, replacing Circadin® which will remain as an alternative as requested by CAMHS teams as part of the updated SCP. For a comparative dose (i.e., 2mg), Adaflex® is similar in price to Circadin® (£15.30 per 30 tablets compared to £15.39). The product licence for Adaflex® allows for crushing and mixing with water before administration. It was noted in this application that melatonin for this indication no longer meets criteria for shared care, though melatonin is currently amber for use in children in Greater Manchester. CRG were generally happy with this being the first line option for melatonin, and for use in those who cannot take tablets it is licensed to be crushed and mixed with water. A discussion was then had regarding its RAG status. It was noted that the initial discussion on this topic (in February 2014 at the New Therapies Subgroup), a specialist discussed melatonin with the group as the intention had been to not recommend its use due to poor evidence base for efficacy. Following this meeting a policy was published that the use of melatonin would be reviewed every six months by a specialist and prescribing would be under a SCP. Concern was raised over the inconsistency of specialist review with current therapy, and that if melatonin moves to a Green SI RAG status, there is less onus on the specialist teams to review and so this situation may worsen. The risk of overprescribing if this was Green SI was also discussed, with patient safety factors (e.g., overdose or interaction) and cost highlighted as concerns. The risk of setting a precedence for moving to Green SI (from Amber) because reviews are not happening rather than because they don't *need* to happen was also discussed. CRG noted that this was being proposed for Green SI based on service capacity considerations within CAMHS, rather than because of it being the most appropriate option for patient care. Primary care management will not act as a fix for this, and we may still see problems with service access.

	It was also noted that the management of adults that no longer fall under CAMHS needs to be considered, and deprescribing recommendations for these groups should be included in the updated SCP being developed. **<u>Decision</u>: Approved to open for consultation for Adaflex® as a first-line formulary option within its licensing for paediatric patients.** **<u>Decision</u>: Melatonin to retain Amber (Shared Care Protocol) status at present.**
3.3	**Mexiletine RAG review** Currently, mexiletine has no RAG status within Greater Manchester. This proposal is for a red status for life-threatening ventricular arrhythmias, which would not require use in primary care. In the last 12 months, 24 items were issued from primary care (at a cost of £30,509) but use for myotonia would be tariff-excluded in line with NICE TA748. Essentially, this would be red for all indications. **<u>Decision:</u> Approved to open for consultation as RED**
3.4	**Chapter 13 Emollients update** It has been highlighted that the emollients within the GMMMG formulary do not align with the products in the emollient ladder document. This update to the formulary reflects the emollients ladder. The ladder is due for update but this will take some time, so the formulary chapter updated to reflect current ladder. One product (Diprobase®) has been discontinued, so a note will be added to the formulary to explain may not be available. Products are listed in order of cost. Was noted about lack of proviso in formulary about duration of use and prescribing but it was clarified that this matches the emollient ladder's lack of proviso. **<u>Decision:</u> Approved to go to GMMMG for ratification**
4.0 Pathways and Clinical Guidelines	
4.1	**Inclisiran prescriber information leaflet** CRG previously reviewed a draft version of this leaflet in March 2022, and it was approved for consultation. Consultation feedback has been received and incorporated (where appropriate) into this current draft. The aim is to aid primary care physicians in feeling comfortable prescribing a new medicine. This is a final version for approval to go onto the GMMMG website. Icosapent Ethyl (Ethyl eicosapentaenoic acid) was discussed during this part of the discussion and this discussion is included in AOB (1). **<u>Decision:</u> Approved for ratification by GMMMG**
4.2	**Levonorgestrel IUS comparison table update** The comparison table has had minor updates to amend costs and efficacy of products, and to clarify the daily dose of levonorgestrel with each product. Licensing of Levosert® is 6 years, not 5 years, which affects the cost-efficacy, too. **<u>Decision:</u> Update approved for ratification by GMMMG**

5.0 Shared care	
5.1	**Patiromer and Sodium Zirconium Cyclosilicate (SZC) SCPs** It was noted that the NHS England Shared Care Protocols were published Friday 8th July 2022. At the March 2022 CRG meeting, it was decided that an amber RAG status would be appropriate for both patiromer and sodium zirconium cyclosilicate. At the time, draft shared care protocols (SCPs) were presented, though there were formatting concerns and other issues identified which needed clarification. Both the patiromer and sodium zirconium cyclosilicate draft SCPs presented at the meeting reflect this update process. Concern was raised regarding the phrasing of GP monitoring requirements, specifically regarding weekly potassium and monthly bicarbonate monitoring. The interval was noted as a concern for primary care workload, and the lack of familiarity with the condition, and with interpreting bicarbonate blood tests, highlighted as a concern for safety. It was also noted that the phrasing for serum potassium monitoring, "Serum potassium should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration", is too vague for a shared care protocol and potentially unsafe. It was also noted that the threshold for "clinically indicated" is likely going to differ between authors (specialists in area) and GPs (who are unfamiliar with use). It was noted that in Bolton FT, junior doctors are not allowed to prescribe these agents without clear explicit directions on what to give (from specialist intensivist or renal medicine registrar) and would not be responsible for monitoring. The ongoing prescribing of these items (130 of sodium zirconium cyclosilicate, and 13 of patiromer, in the last quarter in Greater Manchester) was flagged as a concern, as these are currently considered RED. CRG reconsidered if Amber was the most appropriate status but recognised that other areas have these agents as shared care or green specialist initiation. In order to progress this work CRG agreed to open for consultation and make amendments once this process has completed. **<u>Decision</u>: Patiromer and sodium zirconium cyclosilicate SCPs to be opened for consultation**
5.2	**Growth hormone in paediatrics SCP (technical update)** This is a technical update to change the listed products following the discontinuation of Norditropin cartridges (transferring Norditropin SimpleXx cartridges to the FlexPro and Nordiflex pre-filled pens), and to transfer the contents to the current GMMMG SCP template. **<u>Decision</u>: Somatropin (growth hormone) SCP technical update approved to go to GMMMG for ratification**
5.3	**Dermatology SCPs (technical update)** This is a technical update to add a box with contact details to the letter to GPs for four SCPs (Azathioprine, Hydroxychloroquine, Methotrexate, and Mycophenolate) used in the oral dermatology clinic. The initial ask was for their contact details to be added, but as this is used across GM a section with text boxes to complete was added instead. There is also an option to clarify whether emailed and/or faxed return forms are accepted.

	This has not been transferred to the current GMMMG SCP template as it is anticipated that national shared care documents will be published imminently, and these medicines will have a new SCP shortly as a result of this. The clinical information was not reviewed. Noted cannot use fax anymore for patient information, so this to be removed. **Decision: Azathioprine, Hydroxychloroquine, Methotrexate, Mycophenolate SCPs technical update approved to go to GMMMG for ratification** **Decision: SCP technical update approved to go to GMMMG for ratification** **Decision: SCP technical update approved to go to GMMMG for ratification** **Decision: SCP technical update approved to go to GMMMG for ratification**
6.0 Work plan and horizon scanning	
6.1	**Horizon scanning June 2022** CRG noted the contents of the document, and one item was discussed. **1. Baricitinib: New indication, 'for the treatment of severe alopecia areata in adult patients'** It was noted that alopecia areata is an autoimmune disease, whereas alopecia is normally considered as a cosmetic problem when it comes to formulary decisions, and asked whether we need to issue a position statement regarding this. At Salford, there is a specialist clinic that uses baricitinib for this indication, but as it is not commissioned under the dermatology team the patients have to pay for the prescriptions privately. Whilst some do, the exact numbers (and numbers for Greater Manchester) are unclear. It was noted that baricitinib for this indication is not routinely commissioned in GM but there is a pending NICE TA that is due in April 2023.
7.0 AOB	
	1. Icosapent Ethyl It was noted that the NICE TA for icosapent ethyl is due on the 13th July 2022. (NB, post meeting: This TA has been published as NICE TA805 as planned and is positive.) It was asked whether this guidance would affect the development of the lipid flow chart and guidance, and explained the that accelerated access pathway for lipids is expected to be revised following the publication of the NICE TA. The formulary status was discussed briefly, though it was noted that this is expected next month as a formal application. **2. Publication of national shared care protocols** It was highlighted that 18 shared care protocols were published on the 8th July 2022, and discussed how best to consult on these for GMMMG uptake. It was proposed that GMMMG takes forward the national shared care protocols instead of duplicating work, though highlighted that the format differs from the existing shared care protocols. Concerns were raised with implementation. It was noted that the clinical content is unlikely to change, and agreed broadly by the group that any consultation feedback on these points should be

passed onto NHS England as the group responsible for the content of the documents, and would not be for action by GMMMG, unless a clear error was identified.

The resource impact of having all 18 SCPs out for consultation at the same time was noted, but it was suggested that there is emphasis put on the *implementation* feedback needs (i.e., feedback on adoption), rather than clinical comments, and that consultation is opened for eight weeks instead of six. Given the ask of the consultation comments are likely to be regarding commissioning and service provision, it was suggested these go straight to GMMMG rather than back to CRG.

Action: All 18 of the national shared care protocols (from 8th July 2022) to go for eight-week consultation, with the ask on whether to adopt them (i.e., focus on implementation).

3. **Dexcom ONE Glucose Sensors**

It was noted that as of 1st August 2022, Dexcom ONE Glucose Sensors will be in the Drug Tariff listed at £25 per device. (Cost = £910 a year, similar to Freestyle Libre Sensors.) It was noted that work is ongoing on continuous and flash glucose monitoring, and we do not normally list devices in the formulary, but asked whether a statement be issued to clarify they would be appropriate for use under the same criteria as other glucose sensors.

It was agreed that a discussion at GMMMG may be needed as the current process (led by GM SCN) has not provided an update. It was also noted that despite some concerns nationally about "restricting access", if primary care teams are not in an adequate position to assess, initiate, and train patients, then they could not be expected to start these devices.

4. **SPS and Regional Medicines Optimisation Committee (RMOC) Guidance on Ophthalmic Monitoring with Hydroxychloroquine**

It was highlighted that this guidance has now been published, and a question raised as to whether there are sufficiently commissioned services for these reviews to take place in Greater Manchester (and elsewhere). However the recommendations are within the relevant national SCP and can be identified during the aforementioned consultation.

5. IQoro Device

The IQoro device is listed in the drug tariff, and it was asked whether we need a commissioning position on this device. (Also in NICE MIB176: IQoro for hiatus hernia.) It was noted that the East of England has a "do not prescribe" recommendation, and there is unclear evidence for the efficacy of the device. It was suggested (and agreed) that no review is undertaken or decision is made for now, but this will be revisited if numbers increase.

Date of next meeting: Tuesday 9h August 2022 12:00-14:00 via Teams