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

Name	Title	Organisation	Oct	Nov	Dec	Feb	Mar	Apr
Dr Peter Budden (PB)	GP	St Andrews Medical Practice						✓
Dr Helen Burgess (HB)	GP	Manchester Health and Care Commissioning						✓
Dr Jonathan Schofield(JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓	✓	✓	✓	✓
Sarah Boulger (SBo)	Medicines Information Pharmacist	Pennine Acute	A	✓	A	✓	✓	A
Suzanne Schneider (SS)	Medicines Information Pharmacist	Bolton FT	A	✓	✓	✓	✓	A
Gary Masterman (GM)	Associate Director of Pharmacy	Wrightington, Wigan and Leigh FT	✓	✓	✓	A	✓	A
Andrea Marrosu (AM)	High cost medicines and home care pharmacist	Salford Royal FT	✓	A	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
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	✓	✓	✓	✓	SM
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	A	A	A	A	A
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	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	A	✓	✓	A
Faisal Bokhari (FB)	Deputy Head of Medicines Optimisation	Tameside & Glossop CCG	✓	✓	✓	A	✓	✓
Jennifer Bartlett (JB)	Team Leader Neighborhood Integrated Practice Pharmacists	Salford Royal FT	A	✓	✓	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
Consultant Rheumatologist Audrey Low Ben Parker Charlie Flier Dipak Roy Louise Mercer Meghna Jani Sahena Haque		SRFT MFT Stockport TGH Stockport SRFT UHSM	✓ AP	✓ LM	✓ DR	A	✓ AL	✓ AP

Anindita Paul		Bolton						
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	A	A	✓	✓	✓	A
Dan Newsome (DN)	Principal Pharmacist	RDTC	✓	✓	✓	✓	A	✓
Nancy Kane (NK)	Senior medical information scientist	RDTC		✓	A	A	A	✓
Conor McCahill (CM)	Senior Pharmacist	RDTC	A	A	✓	✓	✓	✓
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. Peter Budden (PB), Helen Burgess (HB) joined the group for the first time.
1.2	**Declarations of interest** Previously declared where relevant. No new declarations of interest were submitted.
1.3	**Draft March 2022 CRG Minutes** The March 2022 CRG Minutes were accepted.
1.4	**Action log review** Most items had no updates, the action owners will be approached for updates. **122101–Sitagliptin patent expiry** It was suggested a paper is produced for May 2022 CRG meeting, with the intention of discussing a plan for the pending patent expiry.
1.5	**Update from March 2022 MGSG meeting** CRG was updated that MGSG has now been stood down, as it will be merged with GMMMG to form a Medicines Optimisation Committee which will act as an interim group prior to the formation of the Medicines Board. The IPMO groups and CRG will now report directly to the new group. There are still some ongoing considerations of the particulars of this group and the processes.
2.0 Matters arising	
2.1	**CRG Consultation Feb 2022** **1. Modafinil 100mg and 200mg tablets for excessive sleepiness associated with narcolepsy with or without cataplexy and Parkinson's disease**

At the February meeting it was decided that based on monitoring requirements (specifically, that modafinil has *patient* monitoring rather than *drug* monitoring) that a move to green + specialist initiation would be appropriate, and make it easier for patients to receive long-term medication. Consultation feedback requested that this is maintained as a shared care medicine based on monitoring requirements.

It was highlighted that patients with conditions such as narcolepsy do not typically get discharged from neurology, and so contacting the specialist would not bring the same concerns (with the referral process) as usual. It was agreed that an information leaflet would be useful in this case.

The difference between a safety consideration (and need for shared care protocol) compared to commissioning implication for funding and time was highlighted, and it was agreed, in particular by the primary care clinicians present, that as there were no safety concerns it therefore does not meet criteria for shared care protocol and should remain for green (specialist initiation).

Decision: Keep as green (specialist initiation)

2. **Dacepton® (apomorphine): 10mg/mL [30mg/3mL] solution for injection and 5mg/mL [100mg/20mL] solution for infusion for motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease**

   It was highlighted that considerations around home care are not relevant at this point as it has been considered already, and the process of adding into the existing shared care protocol is underway.

3. **Bempedoic acid used as per NICE TA694**

   The comments regarding the potential alternative RAG status (currently proposed as green with specialist advice) were discussed. The smaller cohort for bempedoic acid (as opposed to inclisiran) and the absence of special monitoring requirements were noted, and that green (specialist advice) fits in with this. It was noted that national guidance has both inclisiran and bempedoic acid as requiring specialist advice before initiation. It was highlighted there is a lack of long-term cardiovascular outcome trial data and so green (i.e., without specialist input) would not be appropriate.

   It was noted that the regional lipid clinics will not have capacity to initiate all patients who required bempedoic acid, and so the use of advice and guidance processes will allow them to be started in primary care but retain specialist input.

   Some patients are statin intolerant and that improving access to bempedoic acid may help ensure appropriate treatment, though also noted that some of those who are intolerant manage to tolerate statins with an appropriate trial under a lipid clinic.

   Decision: Keep as green (specialist advice)

4. **TA749: Liraglutide for managing obesity in people aged 12 to 17 years (terminated appraisal)**

   One comment queried the proposed paediatric DNP status as there is a possible desire to use in tertiary paediatric obesity clinics due to there being no negative NICE opinion. However, the NICE appraisal was terminated due to the licence holder 'considering that there is not enough evidence to provide an evidence submission', and in light of this CRG did not think it appropriate to make liraglutide routinely available for this patient group. However, if there is a

	patient group for who this may be beneficial, the clinician(s) involved are invited to make a formulary application. **5. TA599: Sodium zirconium cyclosilicate for treating hyperkalaemia (update)** The group heard that the RAG review process is still underway. *No other items were discussed, and no comments were received for other items.* **Action**: RDTC to submit actions to GMMMG for approval.
3.0 Formulary and RAG	
3.1	**Formulary Amendments March 2022** CRG approved the formulary amendments to open for consultation and noted the following: **1. TA773: Empagliflozin for treating chronic heart failure with reduced ejection fraction** CRG in agreement to amend formulary as suggested (Add to chapter 2 as a Green Specialist Advice, with a link to TA773). This item was also discussed as AOB; see AOB (2). 2. **NG91 Otitis media (acute): antimicrobial prescribing** It was suggested that a formulary addition of phenazone with lidocaine eardrops (i.e., in line with NG91) may help prevent inappropriate antibiotic use for ear infections, though noted that an addition would give no direction on when to use. It was suggested inclusion within the regional guidance would be helpful, which would fall under the remit of the antimicrobial stewardship group. **Decision: Add phenazone + lidocaine eardrops to the formulary (as green), and ask antimicrobial stewardship group for incorporation into new antimicrobial guidelines.** **3. NG17: Type 1 diabetes in adults: diagnosis and management,** and **NG18: Diabetes (type 1 and type 2) in children and young people: diagnosis and management** These items were discussed in tandem as there were similar recommendations regarding flash and continuous glucose monitoring. It was noted that both items come with a substantial cost impact, though may improve equality of access (compared to IFRs) It was noted that the current Greater Manchester guidance on flash glucose monitoring is now under review as will need to take these updates into account. It was suggested we discuss this properly, perhaps at the May 2022 CRG meeting. It was noted this also comes under EUR policy (for continuous glucose monitoring), and it was suggested this review could also take place in collaboration with the SCN.

	Due to costs and requirements for a trial of flash glucose monitoring (before moving to continuous), it was suggested that a treatment pathway and monitoring of use would be helpful. **Action**: RDTC / JCT to reach out to SCN and EUR to coordinate next steps. **Decision**: Discuss at May or June 2022 CRG meeting. (It was noted that as this comes from a guideline and not a TA there is not mandatory access timescale but that patient pressure on clinicians necessitates a timely response.) **Action:** RDTC to open formulary amendments for GMMMG consultation
3.2	**DOAC choice for AF (National procurement exercise)** It was explained that there is an ongoing task to look at the national procurement changes for DOACs (that is, that NHS England recommends edoxaban as a first-line choice for AF, where in line with criteria in relevant TAs), and whether CRG is happy to recommend edoxaban as the first-line DOAC for eligible patients for the GM area. It was also asked if we are considering switches from other DOACs, as GM is relatively low in use of edoxaban, and it was suggested that other areas (such as Cheshire and Merseyside) are pursuing this course. The group reviewed documents from the RDTC and Cheshire and Merseyside, and agreed they were useful. The current intention is for RDTC documents to be produced (using their processes, rather than the GMMMG processes) which can then be used within the GM area to inform practice. The group were broadly happy with this with the aim of avoiding a further delay. A GM-wide position statement on DOAC choice was proposed and it was agreed it would be helpful to inform clinical practice. The intention would be to support edoxaban as the first-line agent if suitable in individual cases, in line with NHS England guidance. There was less agreement regarding switching currently stable patients from other DOACs to edoxaban, though a suggestion that unstable patients may be suitable for changes in some cases. The relatively low prescribing rates of edoxaban (and high rates of apixaban prescribing) in the Greater Manchester area were highlighted and that the work required to meet the IIF thresholds may be too great for the available reward, and some PCNs may decline to pursue this indicator. Group members (and colleagues within the NHS) are encouraged to send feedback regarding the RDTC documentation to the GMMMG enquiries email address. (nuth.enquiries.gmmmg@nhs.net) **Action:** Feedback to be passed to RDTC (via nuth.enquiries.gmmmg@nhs.net) on documents in development for DOACs.
3.3	**RAG review: antimuscarinics for hypersalivation** PB chaired this item as AW had to step away briefly. It was explained that this was initially a GM pathway request, however it did not seem appropriate to progress it as one as it did not affect primary care, as these requests all go through a speech and language therapist (SLT) in secondary care with specialist input. This request is for green (specialist initiation) RAG status for hyoscine hydrobromide 150mg and 300mg tablets (Joy-rides® and Kwells®, off-label), hyoscine 1.5mg/72hrs transdermal patch (off-label) and atropine 1% eye drops administered orally (unlicensed). Whilst these items are already used, there is often querying with medicines optimisation team, and unclear place in therapy.

	Cost was clarified during discussion, and 10mL of atropine eye drops are listed in the drug tariff as ~£193 per bottle, which is an increase of £22 in the month since this application was submitted. It was also suggested that minims atropine eye drops could be considered if cheaper. There are also possible cost considerations with glycopyrronium formulation choice (though not considered here. It was also suggested that there may be a cross-over with palliative care teams, and that may explain why the prescribing of some of the more costly options (i.e., glycopyrronium) are higher. **Action**: RDTC to feedback to the pathway authors, and request the agents be placed in a simple treatment algorithm to provide assurance that the more cost-effective agents are used where possible
3.4	**DNP assessment: simple eye ointment** This proposal is for DNP status (Criterion 2: Cost-effectiveness) for simple eye ointment. There is a marked increase in cost when compared to other ophthalmic lubricants, and it was noted that when requests come through for nocturnal eye ointment, they rarely contain a brand recommendation. No advantage to the use of simple eye ointment as opposed to other products, and group broadly in agreement for DNP status. GM spends a total of £226k on prescribing of these items per year, of which, over £180k could be saved if a full switch was implemented. **Action:** RDTC to open for consultation for DNP status
3.5	**Update to formulary respiratory chapter to reflect asthma pathway** The formulary chapter for respiratory drugs was updated, removing products not in asthma or COPD guidelines and favouring those with a lower carbon profile and/or price, and is pending approval by DoCs and DoFs. It was highlighted that there are dry powder inhalers (DPIs) that are not on the pathway, but have favourable carbon profiles, and that some CCGs may have high prescribing rates for these and so good compliance in terms of carbon footprint. It was clarified there would still be expected to be compliance over time with the formulary with this update, though noted it may take some time for practice to change. AMart noted that there will be assurance monitoring of prescribing in this area which will allow for ongoing monitoring by this group. **Action:** Await outcome of DoCs & DoFs decision. Formulary to be updated as a technical update if the pathway is approved.
3.6	**Formulary application: goserelin and leuprorelin for male breast cancer** *Note that this agenda item was jointly discussed with item 5.1 (the draft SCP for goserelin and leuprorelin for Male Breast Cancer)* It was explained there is a patient safety concern due to the out of date SCP, which is specific to female patients. The request has come from The Christie to update the SCP into the new template and to add treatment for male breast cancer to the document. This raised an issue of equality which could be resolved with the proposed update. Male patients currently have to collect these medicines from hospital, whereas female patients can access from their GP under a SCP. It is estimated this will affect six (6) patients per year and was noted that the monitoring is the same as for female patients. Language choice (i.e., male & female, men & women, or patients) was

	discussed with the aim of making the SCP as inclusive as possible. It was noted that licensing will always be an issue with this indication due to lack of data and impetus to apply for licence extension due to small cohorts. It was clarified that although there may be predominantly *patient*-monitoring (rather than *drug*-monitoring) requirements, a SCP would still be suitable due to treatment-associated ADRs and to align with current practice for female patients. It was highlighted to CRG that this merging of drugs (i.e., SCP based on *indication*) goes against some RMOC principles which state SCP should be "drug specific". It was also noted that this request initially came as two protocols, for advanced and early breast cancer, the current SCP has been drafted as a single document, with author approval, for simplicity. It was suggested that the draft SCP be approved for now to avoid ongoing inequality, and then revisions can take place in future. **Action:** RDTC to amend the language as above, and open the updated SCP for consultation
3.7	**Formulary application: Ostenil plus (hyaluronic acid 2%)** This product (generic hyaluronic acid 2%) is currently listed within the formulary as a DNP for this indication under criterion 1. (Criterion 1: Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.) Additionally, this is a NICE 'do not do' (NICE CG177). The evidence that was submitted in support of this application was reviewed and was found to be of relatively poor methodological quality. Some of these studies may support viscosupplementation as a *practice*, but it isn't clear how they support the use of hyaluronic acid (generic or branded). As such it is difficult to state whether they support moving away from a DNP status for this item. A literature search revealed no clear link between intra-articular corticosteroid injections and an increased risk of COVID-19 infection. The group broadly agreed, though there was some discussion on whether expert opinion (i.e., the applicant) should be taken into account. It was noted that to overturn an existing DNP and NICE "Do Not Do" statement the evidence should be of a high quality. The cost-comparison for this item (compared to corticosteroid injection) was difficult to assess as there are no direct cost-comparison studies. It was noted that this is a historical Salford Royal Hospital use, with the orthopaedic directorate funding the treatment from a departmental budget as this is not approved locally, either. It was highlighted this may be an EUR policy concern which also states to not routinely prescribe for this indication. A potential conflict of interest in the application (the drug company funds certain activities for the principle author) was noted. CRG was reminded that the decision should be on the evidence presented in the application and presented as part of the review process, and on that basis a decision was made to <u>not</u> approve Ostenil® Plus. **Action:** Ostenil ® Plus was not approved for consultation on the basis of lack of evidence of efficacy. (Maintains current DNP status, criterion 1.)
4.0 Pathways and Clinical Guidelines	
4.1	**GM standards for inclisiran prescribing**

	CRG were presented with some draft quality standards for use in GM to support the prescribing of inclisiran in primary care, as requested by GMMMG. It was explained that the standards take into account concerns that were expressed by lipidologists in a letter to GMMMG. The standards were considered unecessarily complex and might be more useful and easier to audit against if broken down into smaller sections, and therefore do not all need to be taken forward. It was noted that measures 1 and 2 measure the same standrads, and so only one should be retained. It was noted that measure 4 is more specific than measure 2, too, regarding the target, though both have the same denominator. It was suggested that there is a need to ensure patients have been on an appropriate statin +/- ezetimibe trial prior to being deemed 'intolerant', and that statin +/- ezetimibe use continues whilst on inclisiran. The issues of data collection were raised, specifically as there are system and coding differences between areas and individuals. The lack of GMMMG pathway for inclisiran use was also noted as a problem with inclisiran, and some GPs are refusing to prescribe ongoing treatment even after lipid clinic assessment and recommendation due to a lack of a GM pathway. **Action**: AMart to review the standards, and consider a discussion with the GMMMG digital group before taking forward to GMMMG for approval
5.0 Shared care	
5.1	**Draft GMMMG SCP: Goserelin and leuprorelin in adults for breast cancer** This discussion was undertaken at the same time as 3.6: Formulary application: goserelin and leuprorelin for male breast cancer. **Decision:** SCP update approved to go out to consultation, pending minor amendments around terminology ('male' and 'female', or 'patients') for inclusivity.
6.0 Work plan and horizon scanning	
6.1	**Horizon scanning March 2022** CRG noted the contents of the document, but did not think any required discussion.
6.2	**MGSG work plan** Received for information, a new work plan is in development and will subsequently replace this document.

7.0 AOB

1. **Chair Handover**

   Andrew White formally handed over duties of chair to Peter Budden, and thanked the group.

2. **Empagliflozin for heart failure (discussion during agenda item 3.1)**

   It was noted that there may be appetite to use empagliflozin for hypertension management in those with T2DM. It was highlighted that evidence for this appeared in the American Heart Association Journal, and there were optimal outcomes for blood pressure management which were perhaps linked with weight reduction.

   It was suggested this could be considered as part of a formulary application for that specific use, and it was noted that there is ongoing SCN work regarding an update to the North West Hypertension Pathway.

	It was highlighted to the group that there is a pending launch of a “GM Cardiorenal Metabolic Pathway”, which has not come via CRG (or GMMMG). It was clarified that the RDTC have contacted the pathway authors regarding this to ask if it can be bought into the GM processes.
Date of next meeting: Tuesday 10th May 2022 12:00-14:00 via Teams	