Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday March 8th 2022, 12:00-14:00
via MS Teams

Name	Title	Organisation	Aug	Sep	Oct	Nov	Dec	Feb	Mar
Dr Connie Chen (CC)	GP Lead Medicines Optimisation	Manchester Health and Care Commissioning	✓	✓	✓	✓	✓	✓	✓
Dr Hina Siddiqi (HS)	GP		A	A	A	A	A	A	A
Dr Jonathan Schofield(JS)	Consultant physician acute medicine & diabetes	Manchester FT	A	✓	✓	✓	✓	✓	✓
Sarah Boulger (SBo)	Medicines Information Pharmacist	Pennine Acute	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	✓
Andrea Marrosu (AM)	High cost medicines and home care pharmacist	Salford Royal FT	A	✓	✓	A	A	✓	A
Peter Marks (PM)	LPC Board Member	GM LPC	A	A	A	A	A	A	A
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	A	A	✓	✓	✓	✓	✓
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	A	✓	✓	✓	✓	✓
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	✓	✓	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	✓	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	A	✓	✓ AH	✓	✓
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG	✓	✓	✓	✓	✓	✓	✓
Jacqueline Coleman (JC)	Medicines Optimisation, Interface Pharmacist	Stockport CCG							✓
Consultant Rheumatologist Audrey Low Ben Parker Charlie Flier Dipak Roy Louise Mercer Meghna Jani Sahena Haque		SRFT MFT Stockport TGH Stockport SRFT UHSM	✓ AL	A	✓ AP	✓ LM	✓ DR	A	✓ AL

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

1. General Business	
1.1	**Welcome and apologies** The chair welcomed the group and noted apologies as above. Jude Allen attended to support item 3.3 only.
1.2	**Declarations of interest** None declared.
1.3	**Draft February 2022 CRG Minutes** No concerns were raised regarding the accuracy of the CRG February 2022 meeting minutes, and the minutes were agreed as a true record.
1.4	**Action log review** **1. 05212.1—NG196 – Availability of ORBIT bleeding risk tool.** AMart confirmed has not heard anything more regarding the EMIS update for the ORBIT tool. JH noted that Bolton CCG were informed that EMIS now have an AF section which may contain the tool but they are trying to get confirmation and details of how to access. AMart will try contacting EMIS again. **2. 08213.3—Update to Acne section of formulary** It was confirmed that a new draft is currently in progress. **3. 08215.2—SCP for melatonin in children and adolescents** It was noted that LO is currently awaiting the return of extra information (as requested by MGSG). It was also highlighted that a new licensed formulation of melatonin (for sleep issues in paediatric patients) is incoming. It would be an alternative option to Slenyto® and would likely be cheaper. **4. 09211—Testosterone for delayed puberty**

	LO has chased this, and the specialist team have been made aware. **5. 09212 Vitamin D Guidance** It was highlighted that this work is still ongoing and that the Health Inequalities Group met on 7th March 2022, with a view to focus on care home or maternity patients for implementation. **6. 10211 Paediatric CF drugs RAG** It was confirmed that this item has gone to MGSG, and a draft letter is being produced to send to NHS England regarding repatriation arrangements. It was agreed to remove from the CRG action log for now.
1.5	**Update from February 2022 MGSG meeting** The Asthma pathway was approved, however, there are potential financial implications, and so it has been referred to GMMMG for approval. A Blueteq form for fremanezumab was also approved. All submitted CRG actions were approved.
2.0 Matters arising	
2.1	**CRG Consultation Dec 2021** **1. Micronised progesterone (Utrogestan®) vaginal 200mg capsules for prevention of miscarriage** A comment was received from a consultant gynaecologist regarding the proposed RED RAG status. It was suggested that due to utrogestan being a "low cost and safe treatment with proven cost-effectiveness", it should be able to be offered in the "primary care setting at the point of presentation with symptoms and women should be able to obtain on-going prescription locally until 16 weeks rather than reattending emergency services to obtain treatment in the event their pregnancy continues." These scenarios would lend themselves to a GREEN status (with or without specialist involvement). However, CRG noted that NG126 Ectopic pregnancy and miscarriage: diagnosis and initial management specifies that a scan is required to confirm an intrauterine pregnancy prior to treatment, which would necessitate secondary care involvement. It would therefore be at least be a Green following Specialist Initiation as primary care would be unable to perform the required scans, but could possibly continue prescribing on specialist direction. It was noted that in terms of access to scans, most women across Greater Manchester would be able to access Early Pregnancy Units (EPU). It was highlighted that if there will be primary care prescribing, it would be worthwhile ensuring that GPs are aware of the use of the medicine, in order to avoid confusion on referrals and additional patient stress if there are concerns/pushbacks to prescribing following specialist referral to primary care. The group however leaned towards maintaining a RED RAG status with consideration to the following: • These patients would tend to be followed up by the EPU who would also be providing support beyond the issuing of prescriptions. It seems sensible for the full course to be supplied by them, as a one stop shop for the patient's journey. • Concerns were raised regarding adequate and timely communication to primary care of what is needed which can lead to patients being caught in the middle. • There were also some concerns about familiarity with the drug for this indication and how/ whether community pharmacists would be able to handle this

	The group agreed to defer the decision as it was felt that wider consultation with specialist teams was needed to determine if there are significant reasons that this treatment should not be RED. **Action**: Secondary care reps were requested to consult with their relevant specialist teams as per above and feedback at the next meeting. **2. Inhaled Budesonide for COVID** Following the NICE COVID guideline update and CAS alert that inhaled budesonide should only be used for COVID in the context of a clinical trial, it was agreed that the formulary be amended to reflect this update. A comment was received noting that respiratory SCN leads are still in favour of budesonide for this indication, despite recommendations from NICE, as they feel that it would be clinically beneficial to patients. The same trials that NICE used to recommend against the use of budesonide for this indication were referenced. When the comment was originally received, a response was sent indicating that CRG were acting in line with the NICE guidance and the CAS alert, and that the group couldn't recommend against following them without strong evidence to do so. Notably, NICE noted that there were no significant differences in hospitalisation, death, or mechanical ventilation requirements with inhaled budesonide. And while there is some suggestion that it may be beneficial for recovery times, the evidence only comes from 2 trials, one of which was very small and finished early. The group agreed that the status of budesonide for COVID is maintained as per the NICE guidance and CAS alert. AW to respond to commenter on behalf of the group. ***Post meeting note**: Correspondence received from clinical director of the CMDU via AW: "I am also inclined to follow the NICE guidance. There is no difference between the 2 groups around the endpoint of hospitalisation and death. The observations around symptomatic improvement are interesting but difficult to interpret in patients in an open label trial who know they are getting treatment."* **Action**: RDTC to submit actions (except utrogestan) to MGSG for approval.
3.0 Formulary and RAG	
3.1	**Formulary Amendments Feb 2022** CRG approved the formulary amendments to open for consultation and noted the following: **1.** NICE TA769: Palforzia for treating peanut allergy in children and young people It was agreed to add Palforzia to the paediatric RAG list as a RED drug, and to add to formulary and grey list as a RED drug: only for use in people aged 18 and over if treatment started between the ages of 4 to 17, as per NICE guidance. Palforzia is expected to be provided in allergy clinics within NHS Trusts. NICE notes only around 20 allergy clinics across the country will be able to provide the treatment in the first 5 years. It was discussed that whilst a RED RAG is appropriate at this time, there's a likelihood of allergy clinics perhaps seeking transfer to primary care for patients on long term treatment. Therefore there's a possibility that the RAG may need to be reconsidered in the future. **2. NG28: Type 2 Diabetes Mellitus (T2DM) guideline update** It was noted that MGSG discussed the need for a local T2DM guideline in light of recent updates to NG28 (Type 2 diabetes in adults). RDTC have been in touch with the SCN to find out where plans

	and aim for joint working. The formulary will need to be updated in accordance with any local guidance produced. **3. Moxonidine (clarification of RAG status)** A query was submitted regarding the RAG status of moxonidine. It is currently listed in section 2.5.2 of GM formulary as specialist initiation only, but without a RAG status. It was noted that usually, if no specific status is indicated for established drugs, then GREEN is assumed. There were no reasons identified to limit the drug to specialist prescribing only. It was felt that GPs wouldn't start this item, but could continue it. It was agreed that the RAG status could be clarified to GREEN following specialist initiation. **Action:** RDTC to open formulary amendments for GMMMG consultation as appropriate.
3.2	**Formulary Application: Nebulised Gentamicin and Tobramycin for Non-Cystic Fibrosis Bronchiectasis** This was a request from the MFT respiratory team for addition to the formulary of gentamicin and tobramycin solutions for injection to be used as nebuliser solutions for patients with non-cystic fibrosis (CF) bronchiectasis colonised with Pseudomonas who cannot tolerate or do not respond to colistin injection. It was clarified that this would be an off-label use of the injections. Tobramycin does have a licensed nebuliser solution available (see SPC), but these are licensed for use in CF patients, and are expensive. Use of the nebulised liquid form of tobramycin would therefore be off-label, albeit the same route. Gentamicin doesn't have a nebulised solution, so the only option in this case is to use the injection via a nebuliser. It was noted that the formulary application refers to the British Thoracic Society guidelines on bronchiectasis in adults to support the clinical use of these agents. Safety concerns were discussed with this application, particularly surrounding the use of tobramycin solution for injection. If using tobramycin solution for injection as a nebuliser solution, it is critical that a phenol free solution is used as the inhalation of phenol is associated with many adverse effects. There were concerns about how this can be ensured in primary care; it was discussed that clarifying phenol content of medicines is not always as simple as looking at an excipient list. The application specified brands that did not contain phenol Sandoz, Hospira), however feedback was received that these brands don't seem to be readily available in primary care. There were also general concerns regarding the unfamiliarity of these agents to primary care healthcare professionals and how they would cope to ensure safe and appropriate supply. The MHRA advice was highlighted that medicines should only be used outside of their license where no suitable alternative exists – in this case, there is a suitable alternative licensed for this route (the nebulised tobramycin product). While it is acknowledged that licensed products cost more than the injection, the group felt that this did not provide justification for use of the injection, particularly given the safety risk. Patient training on preparing and administering the medicine was also a consideration, but it was noted that the specialist team would be responsible for this. The application was submitted alongside shared care protocols to support an AMBER status, though it was noted that the decision on formulary and RAG status needs to be agreed prior to considering shared care protocol development. Monitoring that would be requested in primary care was included within the SCPs. It was noted that there is variation in the status of these agents in other areas. For example, Pan Mersey have them as an AMBER-Retained (similar to Green Specialist Initiation but patient not

	discharged from specialist service), and they use the licensed tobramycin nebuliser solution. Some areas have them as RED. It was highlighted that no areas were identified that use tobramycin solution for injection in primary care, and this may be due to significant risks if phenol was to be nebulised accidentally. The group noted the very small patient numbers - 14 patients each for gentamicin and tobramycin per year in a wider population of almost 3 million in GM. The group heard that some Trusts in GM already use these agents but keep the prescribing and dispensing in house. This was considered a more appropriate route, given the small and niche population and to ensure safe and appropriate supply. The group were keen to avoid any possibility of these products being pushed to primary by adding them to the formulary. It was also noted that no evidence was provided indicating support from the local medicines management committee and there was an ask for this to be clarified. The group agreed not to approve the addition of gentamicin and tobramycin injections for nebulisation to the formulary taking all of the points raised above into consideration. **Action:** Decision to be fed back to applicant.
3.3	**RAG Review: Patiromer and Sodium Zirconium Cyclosilicate for Hyperkalaemia** Jude Allen (JA) (Specialist Renal Pharmacist, Salford Royal NHS Foundation Trust) led the discussion on this topic. The request was to move patiromer and sodium zirconium cyclosilicate (SZC) to Green following Specialist initiation, or to AMBER, for the treatment of *chronic* hyperkalaemia in adult patients. Shared care protocols (SCPs) were submitted along with the request. It was clarified the intention would not be to use in primary care for emergency, acute treatment (which would remain RED), and that the proposed use would be predominantly from heart failure / renal clinics. In these settings, a lot of patients are elderly and it would be easier if treatment was available closer to home. There is also some current primary care prescribing of these medicines across Greater Manchester. Estimated patient numbers varied; SRFT estimated 60 patients across GM however the NICE estimate is around 300 patients. JA explained that leaflets could be developed to aid GPs with their use, and clarified that monitoring is not too intense/specialist that it couldn't be done in primary care. Some concern was raised over the GP management of monitoring and the interpretation of these results, as typically problems with hyperkalaemia identified in primary care often warrant a referral to secondary care urgently for treatment. JA clarified the main use here would be for optimisation of RAAS therapy, and that if issues are identified with monitoring, patients could be referred back to a specialist. It was noted that there are often concerns with potassium levels in these patients anyway, and so the addition of a medication with the aim of helping this (i.e. by normalising/stabilising serum potassium) is likely to reduce problems in primary care, not create more). It gives more opportunity to treat with RAAS in patients that may otherwise be unable to tolerate them (due to hyperkalaemia). It was asked whether there would be some risk associated with moving chronic hyperkalaemia treatment more towards primary care, if RAAS therapy is managed by specialist clinics, and if titration of these agents were being done separately. It was noted by JA that whilst RAAS therapy is often monitored by specialists in these cases, this change would make continuation of care for hyperkalaemia easier. It was also suggested that by reducing demands on secondary care for monitoring appointments, there would be a potentially increased capacity for treatment for other patients.

	There was some discussion regarding some content of the SCP i.e. “review […] as directed” being less clear for primary care, and that complex patient condition may complicate this further. Clearer guidance would be required on this in the SCP. Also in the instances where “stable” is used, there would need to be clearer guidance around this. Questions were also raised regarding what cut-offs would be; for example, serum magnesium measurement references ranges differ between GM biochemistry laboratories. JA suggested with regards to these points that she can discuss this with the author of the monitoring section of the SCPs. Though there was some question as to whether the drugs would fit the RMOC criteria for shared care, overall, the group felt that an AMBER status would be more appropriate given the monitoring required of primary care and to provide the guidance needed for the safe management of these patients. It was noted that the current draft SCPs are not in the correct template and will need to be transferred into the current GMMMG template. The group agreed to putting out the SCPs for consultation following the requested amendments. **Action**: Once updated, proposal (and draft protocol) to go for consultation for AMBER RAG status.
3.4	**Inclisiran Prescriber Information Leaflet** There was a request from GMMMG that a prescriber information leaflet was developed in order to support a quality standard regarding the prescribing of inclisiran. The current training slideshow for inclisiran is 85 slides, and contains quite a lot of information. A leaflet was developed, using one originally developed by Tameside and Glossop CCG to aid in the process. It was clarified that the current document is a starting document and is not necessarily the finished article. The current draft also lacks stopping criteria, and it was suggested that this should be added. FB kindly shared some additional guidance developed by Tameside and Glossop which has a flowchart and links to other resources and was happy for this to be incorporated into the leaflet. It was noted that this document doesn’t show who is eligible, whereas the national AAC lipid guidance does which could also be incorporated as appropriate. CF also volunteered to share a document produced by MHCC. It was suggested that reference to ‘e-referral’ should be amended to ‘local referral process’ to cover all local situations. It was also suggested that mentions of statins and ezetimibe should be caveated ‘if clinically appropriate’ as they will not be suitable for everyone. CC informed the group that the MFT paediatric team were looking at inclisiran for paediatric use (unlicensed). The group were happy for the document to go out for consultation following the amendments. JS was happy to look over the document before it goes out for consultation. **Decision:** To go out for consultation following amendments.
4.0 Pathways and Clinical Guidelines	
4.1	**GMMMG Neuropathic Pain Guidance (Post Consultation)** This was a technical review of the guidance. KO worked on this and brought an updated version to November 2021 meeting of CRG. Comments from this were enacted prior to December 2021 meeting of CRG, at which point it went out to consultation. The consultation period is now finished and consultation comments (which were attached) have been reviewed and acted upon as appropriate. The version presented in March 2022 CRG is the final draft. GM Joint Formulary section 4.7.3 on neuropathic pain was also updated to reflect NICE CG173 and the GMMMG

	revised guidance. No significant resource impact is anticipated although there may be minor financial implications through change of product mix. The DNP (do not prescribe) list was discussed with regards to gabapentinoids to sciatica. It was noted that similar discussions have taken place before, and it was felt that DNP should ideally be reserved for medicines that are *never* to be used, rather than in a case like this where gabapentinoids do have a use, but not appropriate to be used in a certain situation. It was noted that NICE "Do Not Dos" have somewhat evolved and now include many such scenarios of not using drugs in specific conditions rather than not using them at all. An attempt to DNP all such scenarios would require a lot of resource. There is also no longer a list maintained by NICE of all their Do Not Do recommendations making it difficult to keep up with all the various recommendations. There is therefore potential for inconsistency within the RAG list/ formulary if all of these recommendations are not captured. It was suggested and agreed that these Do Not Dos can be added to the notes section in the relevant part of the formulary. **Decision**: Updated guidance and formulary section approved to go to MGSG for approval.
5.0 Shared care	
6.0 Work plan and horizon scanning	
6.1	**Horizon scanning Feb 2022** Items noted included: **1. Generic Betamethasone/Calcipotriol Cream** Now off patent, will be a competitor for Dovobet®. **2. Filgotinib** New indication approved for active ulcerative colitis. NICE due to report in early June. If positive, will need to add to IBD pathway. 3. **Vildagliptin** Vildagliptin patent expires in September 2022, as does sitagliptin (discussed previously in CRG). We may need to look at this alongside sitagliptin. **4. Inhaler devices for salmeterol/fluticasone** New devices approved. Neither are in guidance that has gone through this group. There is a view that there is a need to cull respiratory formulary as it is getting too bloated with devices. There might be scope to work on costs/rebates/pMDI, and it may fall outside formulary RAG status.
6.2	**MGSG work plan** Received for information.
7.0 AOB **1. DOAC choice** There is work in progress reviewing edoxaban as first line choice and switching with the aim of coming back for the April 2022 CRG meeting. AW noted also national work ongoing and clarification is being sought on certain aspects of this, particularly with regard to first line / switching. **2. Pre-filled syringe glucagon.** New pre-filled syringes of glucagon, which are likely more expensive than other forms. It was highlighted that we need to be aware of this as they are being marketed. JS not aware of formulary application coming in regarding this item, but aware of discussions in primary care.	

3. **Thank you to Connie Chen.**

   AW led the group in giving their thanks to Connie Chen for her involvement with medicines management over many years, and being a pioneer within this field in Greater Manchester.

AW asked that if anyone knows any GPs wanting to join CRG then to let the group know.

Date of next meeting: Tuesday 12th April 2022 12:00-14:00 via Teams