Minutes of the GMMMG Clinical Reference Group Meeting
Tuesday July 13th 2021, 12:00-14:00
via MS Teams

Name	Title	Organisation	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Dr Connie Chen (CC)	GP Lead Medicines Optimisation	Manchester Health and Care Commissioning	✓	✓	✓	✓					
Dr Hina Siddiqi (HS)	GP		A	A	A	A					
Dr Jonathan Schofield (JS)	Consultant physician acute medicine & diabetes	Manchester FT	✓	✓	✓	A					
Lisa Kershaw (LK)	Lead Medicines Optimisation Pharmacist	Manchester FT	A (VR)	✓	A	A					
Sarah Boulger (SB)	Medicines Information Pharmacist	Penine Acute	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	✓	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					
Keith Pearson (KP)	Head of Medicines Optimisation	Heywood, Middleton & Rochdale CCG	✓	✓	✓	✓					
Lucy Tetler (LT)	Medicines Optimisation Pharmacist	Bury CCG	✓	A (SK)	✓	✓					
Helen Isherwood (HI)	Medicines Optimisation Pharmacist	Manchester FT	✓	✓	✓	✓					
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	A	✓ (SB)	✓ (SB)	A					

Faduma Abukar (FA)	Head of medicines management	Stockport CCG	✓	A	✓	A					
Zoe Trumper (ZT)	Assistant director of medicines management	Wigan Borough CCG	✓	✓	✓	✓					
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	✓	✓	✓					
Aleksandra Houghton (AH)	Senior Medicines Optimisation Adviser	Manchester Health and Care Commissioning	✓	✓	A (CF)	✓					
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG				✓					
Lizzie Okpara (LO)	Lead Pharmacist Medicines Management	RDTC	✓	✓	✓	✓					
Monica Mason (MM)	Head of Prescribing Support	RDTC	✓	✓	A	A					
Dan Newsome (DN)	Principal Pharmacist	RDTC	A	✓	A	✓					
Andrew White (AW)	Head of Medicines Optimisation	JCT	✓	✓	✓	✓					
Andrew Martin (AMart)	Strategic Medicines Optimisation Pharmacist	JCT	✓	✓	A	✓					
Karina Osowska (KO)	Medicines Optimisation Pharmacist	JCT	A	✓	✓	A					

1. General Business	
1.1	Welcome and apologies (See register for apologies). The meeting was chaired by Andrew White (JCT). DN provided an update regarding group membership. The High Cost Drugs Subgroup has now been stood down and the functions are to be incorporated into CRG and MGSG as appropriate; with CRG looking at clinical/interface matters and MGSG financial and commissioning. Previous group members have been invited to join either CRG or MGSG based on their roles, so CRG can expect some new members attending future meetings. The group welcomed Jole Hannan who attended for the first time.
1.2	**Declarations of interest** None declared.
1.3	**Minutes of the last meeting** The minutes were agreed as a true record following a minor amendment.
1.4	**Action log review** Updates on the action log were noted. It was requested that AMart try to find out from EMIS if they have plans to incorporate the ORBIT tool into the system and if so, when this is likely to be available. AMart noted that the company tends not to deal with non-users but would try. For the action related to updating the PCSK9i guidance to include bempedoic acid, AMart pointed out that while he was happy to approach the authors of the guidance and work with them, attempts to contact them in the past have been unsuccessful, receiving very little or no feedback. It was questioned whether there was really a need for the pathway. Upon further discussion, the group considered that since the agreed status is GREEN following specialist initiation (currently out for consultation), with specialists responsible for ensuring appropriate patient selection in line with the NICE TA, there doesn't appear to be a need for a pathway at this time. HI shared that the application for bempedoic acid submitted to MFT MMC in June estimated 70 patients per year across all MFT sites. The group agreed to adopting/endorsing the RDTC document currently in development on Private Healthcare providers requesting prescriptions from GP services for use in GM, rather than updating the current GM guidance to avoid duplication of work. It was noted that the RDTC document is also being taken through the RMOC system.
1.5	**Update from MGSG** DN provided a summary of discussions and decisions made at the June MGSG meeting. AW gave the update on the alignment of SCP commissioning arrangements. Draft minutes were enclosed which contain further details of the discussions.
2.0 Matters arising	
2.1	**Consultation feedback on May 21 actions** The group noted that one comment had been received from the consultation on the actions proposed in May. This was related to the fact that alendronate 70mg tablets are not licensed in

	men and whether this information would be reflected in the formulary. The group agreed that the formulary could be annotated to state use in men is not licensed but is commonplace. **ACTION**: RDTC to submit May actions with above update to MGSG for ratification.
3.0 Formulary and RAG	
3.1	**Formulary amendments May 2021** Suggested formulary amendments were noted and approved as follows: Budesonide orodispersible tablets (ODT) for inducing remission of eosinophilic oesophagitis to be added to formulary chapter 1.5.2 as GREEN following specialist initiation in line with TA708. The group noted that although budesonide ODT is licensed for both inducing and maintaining remission, TA708 only covers induction of remission (treatment of up to 12 weeks) as this was the only licensed indication at the time the TA was started. It was recognised that now this treatment is NICE approved for inducing remission, clinicians may seek to use it further for maintaining remission and so a GMMMG position on maintenance treatment is necessary. The group were informed that the RDTC would be reviewing use for maintenance treatment and will share this with CRG once available to inform discussions on the position on maintenance treatment. Ravulizumab for treating atypical haemolytic uraemic syndrome to be RED. This is a NHSE commissioned PbRe drug. Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs to be added to formulary chapter 10.1.3 as a RED drug with link to TA711. This is a CCG PbRe drug within the scope of the GMMMG psoriatic arthritis high cost drugs pathway. There was some discussion around limitations to the availability of an updated GMMMG pathway for ankylosing spondylitis and psoriatic arthritis. It was noted that the approval of an updated pathway is currently stalled due to awaiting the approval of an outcomes framework, however there is a need to have a clinically up to date pathway to support clinicians. Further discussions on this are to take place outside of the meeting. The group noted the publication of NG197: Shared decision making. While the guidance contains no medicine specific recommendations requiring action, it was acknowledged that shared decision making and how this can be supported should be an important consideration in the process of producing and approving guidelines/pathways. NG198: Acne vulgaris: management was also noted. AMart mentioned that the relevant formulary section largely aligned with the recommendations in the NICE guidance but could do with some minor tweaks. It was requested that AMart brings a summary of the changes required to the next meeting. Following a formulary amendment request, the group approved a GREEN following specialist advice status for melatonin (Circadin®) for treating REM sleep behaviour disorder in Parkinson's disease. This is in line with NG71: Parkinson's disease in adults (July 2017) which recommends that melatonin should be considered for treatment of REM sleep behaviour disorder in people with Parkinson's disease, if a medicines review has addressed possible pharmacological causes (off-label indication). It was noted that there is no monitoring requirement for primary care and these patients will remain under the supervision of their neurologist with regular reviews for the management of their condition. It was agreed that prescribing in primary care is reasonable; these patients are also likely to be getting supplies of other medicines for their condition from their GP. There was a suggestion that information about crushing Circadin could be included in the formulary. However, this type of information is not routinely included in the formulary and

	would result in inconsistency in formulary entries. Another suggestion was to sign post to resources for information on crushing, but it was pointed out that not all have access to these resources. It was agreed that people could contact their local medicines information service if necessary for information on crushing. **ACTION**: RDTC to open above decisions for GM wide consultation. AMart to submit summary of changes required to acne section of formulary for August meeting.
3.2	**Haloperidol RAG assessment for tic disorders in adults and formulary status of 500 microgram tablets** The group reviewed a RAG assessment for oral haloperidol for treating Tourette's syndrome and other tic disorders in adults. The assessment was prompted by a query from a consultant neuropsychiatrist whose request to a GP practice to prescribe haloperidol for an adult with tic disorder was declined. The patient had been on the medicine since childhood. Haloperidol has a status of RED for treating Tourette's Syndrome and other tic disorders in children and adolescents. However, there is no RAG status for adults for the same indication, so there is a gap where these children become adults and need to continue treatment. Oral haloperidol is included in the adult RAG list as a GREEN drug but this is annotated to state for palliative care use only. A GREEN specialist initiation or GREEN specialist advice status for this indication was suggested. It was noted that haloperidol is the only licensed treatment for this indication and use is supported by European guidelines. The recommended monitoring is ECG at baseline and then as clinically indicated during treatment, and electrolytes at baseline and periodically during treatment. RAG classification in other areas was noted and was generally the equivalent of GREEN specialist advice or initiation. The group were reluctant to assign a GREEN specialist initiation or GREEN specialist advice status. There was some concern that this carries the risk of haloperidol being treated as GREEN for psychiatric indications in particular which are currently managed under shared care. There was also concern about the potential lack of ongoing specialist input once these patients are discharged from paediatric specialist services. It was requested that further information on patient numbers involved and how these patients are currently managed be obtained to further inform the discussion. It was also suggested to seek input from mental health colleagues. The group noted that haloperidol 500 microgram tablets have become very expensive. Following the discontinuation of haloperidol 500 microgram capsules (Serenace®) in 2020, the cost of the 500 microgram tablets has risen steadily over the past year and current cost for 28 tablets is £144.11. Prescribing data showed that between May 2020 and April 2021 GM had spent around £770K in total for oral haloperidol products and around £700k of that was spent on the 500 microgram tablets alone (4538 items). In the previous year, total spend was around £290k with haloperidol 500microgram tablets accounting for £126k of the total spend (4176 items). It was considered that liquid preparations are available – haloperidol 5mg/5mL and 10mg/5mL which are listed on formulary. They are a more cost-effective option for achieving doses that 500 microgram tablets would otherwise be used for. Their cost is significantly less at around £7 for 100mL. Secondary care representatives confirmed that the cost of the 500 microgram tablets is similar in secondary care and the group heard that Manchester, Salford and Bolton Trusts all use the oral liquid instead as a more cost-effective option. CRG agreed to remove the 500 microgram tablets from formulary recognising that the liquid preparations represent better value. It was acknowledged that effective communication of this decision (once finally approved) to clinical teams including local pharmaceutical committee representatives for cascading to community pharmacy teams would be essential to facilitate local implementation

	which was recognised may take a few months. It was also suggested that group members could consider carrying out local audits to help shed more light on the expenditure. **ACTION**: RDTC to request further information as above, and to open recommendation to remove 500 microgram tablets from formulary for GM wide consultation.
3.3	**Deoxycholic acid DNP assessment** The group reviewed a DNP assessment for deoxycholic acid (Belkyra®) for treatment of moderate to severe convexity or fullness associated with submental fat ("double-chin") in adults when the presence of submental fat has an important psychological impact for the patient. The assessment found a lack of robust evidence of clinical effectiveness – this meets criterion 1 of the DNP criteria. The rating scales used to assess the effect of the treatment were not found to be supported by robust data on their validation. There's also no information about how the findings correlate with quality of life or longer-term psychological impact. Also the group previously deemed the indication to be cosmetic, therefore low priority for NHS funding. A DNP status was agreed. **ACTION:** RDTC to open decision for GM wide consultation.
4.0 Pathways and Clinical Guidelines	
	None for this meeting.
5.0 Shared care	
	None for this meeting.
6.0 National and regional guidance	
	None for this meeting.
7.0 Work plan and horizon scanning	
7.1	**RDTC Monthly Horizon scanning June 2021** The group noted the June Horizon Scanning document. DN noted that MGSG had reviewed this document at their last meeting where they noted the EMA positive opinion on the license extension for empagliflozin to include heart failure and EMA positive opinion on setmelanotide for treating obesity due to a rare condition. Both are on the NICE work plan with TAs expected in February 2022 and March 2022 respectively. AMart pointed out Ryeqo (relugolix / estradiol / norethisterone acetate) which has an EMA positive opinion for moderate to severe symptoms of uterine fibroids, noting that this may be of interest given the safety issues that are now associated with ulipristal. The group were informed that RDTC would be scoping this item and will report back the outcome to the group.
7.2	**MGSG and CRG work plan** The current work plan was noted. The work plan will be continually updated with items from MGSG/CRG as these are agreed.

8.0 AOB

Handling of guidance coming in from SCNs and similar networks

JCT have recently received some requests from Strategic Clinical Networks and similar to review guidance they have produced containing medicine recommendations with a view of obtaining a GMMMG stamp of approval. AW asked the group for input on how these should be approached proposing that the approach should be one that is not too onerous but still has appropriate scrutiny and noting that going through the full governance process would require significant resource. There was suggestion that where there's a relevant formulary section, the authors should be advised to adhere to this and this should avoid the need to go through the full governance process. However, incorrect interpretation of the formulary was noted as a concern. It was also mentioned that these networks may not be aware of the current structure of GMMMG and subgroups and some communication to this effect may be useful. Further discussions outside of the meeting to be arranged to discuss an approach that can be proposed for consideration by MGSG/GMMMG.

Freestyle Libre

FB asked if there were any plans to revisit the GMMMG Freestyle Libre (FSL) recommendation. They have recently received queries from GPs about prescribing outside GM recommendations, citing potential inequality issues. AMart noted that the GMMMG recommendation was updated fairly recently to include FSL2 and there are no current plans to update further; however he did have some awareness of the issue raised by FB. FB noted that some local work is being carried out and would feed this into GMMMG if anything significant came of this.

Availability for August meeting

Group members were asked to confirm their availability for the August CRG meeting. It is currently planned to go ahead with this meeting.

Date of next meeting: Tuesday 10th August 12:00-14:00 via Teams