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

Name	Title	Organisation	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Feb
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	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
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	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
Steven Buckley (SB)	Director of pharmacy	GM Mental Health FT	✓ (SB)	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	✓	✓ AH	A	✓ AH	A	✓	✓ AH	✓
Jole Hannan (JH)	CCG Interface Pharmacist	Bolton CCG		✓	✓	✓	✓	✓	✓	✓
Consultant Rheumatologist Audrey Low Ben Parker Charlie Flier Dipak Roy Louise Mercer Meghna Jani Sahena Haque Anindita Paul		SRFT MFT Stockport TGH Stockport SRFT UHSM Bolton			✓ AL	A	✓ AP	✓ LM	✓ DR	A

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
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	A	✓	✓	✓	✓	✓	✓	✓
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. The chair welcomed the following guests; Ricardo Ribeiro Surahbi Wig Dr Paul Cooper for 1.3 Modafinil RAG review Mr Leon Au for 3.2 Steroid Eye Drops
1.2	**Declarations of interest** Declarations of interest have been declared to the Chair previously where relevant. Dr Paul Cooper declared that he has acted as chair of the NICE development group that made recommendation(s) regarding modafinil in excessive sleepiness in Parkinson's disease, and that he is a specialty advisor to NICE for neurology drugs.
1.3	**Modafinil RAG review** CRG reviewed a request to consider a change in the RAG status of modafinil from RED pending shared care protocol (AMBER) to GREEN (Specialist Initiation). Dr Paul Cooper (PC) in attendance to present/provide background. In addition to information in the pre-meeting material, Dr Cooper explained that modafinil has been a well-recognised treatment for ~20 years with minimal-to-no expected adverse effects. The risks of diversion (for abuse, e.g. as a 'study drug') were noted. It was suggested a shared care protocol is superfluous as there are limited monitoring requirements with modafinil; e.g. the SPC notes a need for ongoing blood pressure / heart rates checks, though those on antihypertensives would already be getting regular blood pressure checks, and others could be assessed during annual reviews. It was suggested (and agreed) that it would be sensible for the patient to remain under the overall care of the specialist for follow-up reviews (i.e. as opposed to complete transfer of care to primary care). It was explained that modafinil is actually a RED drug at the moment (pending SCP development), and one reason for this is the commissioning block on shared care protocols being agreed/implemented at the moment. It was noted that a shared care protocol had previously been

	developed and approved, and part of the reason for this returning for discussion is to alleviate patient access problems. It was also noted that there are some patients who have had to go to hospital to collect medication for the last 2-3 years during the pandemic as it cannot be transferred to primary care. There was discussion of patient numbers, and as this relates to an orphan condition which is likely underdiagnosed, it was explained that prevalence (and total patient numbers) are unclear. PC estimated that in GM area ~100 people would fall into the indicated group. It was highlighted that there are approx. 700 items per quarter in primary care in GM area, so an estimate may be 200-300 patients. However as prescribing data doesn't include indication it is unclear how much overlap with PC estimates. Concerns regarding planned follow-up vs. patient-initiated follow-up (PIFU) were raised though it was agreed that annual specialist follow-up (at a minimum) would be appropriate. It was also asked how GPs would identify and refer back if they had concerns – a shared care protocol answers some of these concerns. It was suggested (and agreed) that an information leaflet could accompany prescribing to aid with these concerns. It was also highlighted that some clinic letters contain vague language, such as "you may want to review blood pressure", and it was asked that the language is amended to make the plan clear. The current prescribing situation was discussed. It was highlighted that because of increasing workload and the demands of prescribing on the specialist service, it is unlikely new patients will be initiated on treatment (PC noted new patients are currently not being initiated) if it remains a RED drug due to service being unable to cope. CRG agreed the change to a GREEN (Specialist Initiation) status with the specialist team maintaining overall supervision of the patient and follow up. **Decision:** CRG approved to go for consultation
1.4	**Minutes of the last meeting** The minutes of the December 2021 meeting were discussed. No new comments were raised, though DN (at the RDTC) has previously received comments.
1.5	**Action log review** See action log. It was confirmed that work on lithium blood tests is ongoing (by SB) following a period of absence with an aim to have something ready for the next meeting.
1.6	**Update from January 2022 MGSG meeting** • IBD high cost pathway approved pending GMMMG pathway discussion. • Two high cost pathways in agenda approved for consultation, but not gone out yet as pending final versions. • Tobacco dependence and treatment document was published and is now on the website. • There was a long discussion regarding the inhaled therapies for paediatric cystic fibrosis patients. Decision in CRG was previously for RED and not transferring back to provider, at the moment the status is not going to change as MGSG felt this would cause more problems than it resolved. There is now a pending letter to NHS England regarding the repatriation of services, though if this does not progress things it will be considered at ICS level. • CRG informed that some work on DOAC procurement and choice will come to CRG in future meeting(s). RDTC currently working on clinical information regarding the swap to

	edoxaban as a first-line option. CRG purpose will not be to discuss rebates, just the clinical aspects of a change. Aiming for March 2022 for this. It was highlighted that this work may be useful, but the official national advice is already that this is happening. It was clarified that this work may be useful to help inform clinicians and help with culture change (that may impact prescribing choice). It was also noted that CRG cannot have these discussions purely with respect to rebate cost saving, but as national scheme, this allows CRG to have discussions of clinical choice with consideration to cost savings. Main aim to ensure it isn't a detrimental change. It was suggested that those interested in being involved contact DN at the RDTC.
2.0 Matters arising	
2.1	**CRG Consultation Nov 2021** **1. Trurapi** No comments received on this, so Green RAG status taken forward. **2. Haloperidol 500 microgram tablets (Proposed DNP)** Feedback received regarding small number of patients that may be using in dosette boxes (multi-compartment compliance aids). Changing to liquids would not be appropriate for these patients. It was then asked if this is a legitimate reason to avoid DNP, and it was asked how many patients this affects. It was confirmed by LT that this was raised as a theoretical concern rather than a previously identified problem, but that it may affect some people. As concerns were theoretical, there were no disagreements to this being taken forward for DNP. It was also clarified that this is a longer-term price change which would tend to be picked up if haloperidol 500 microgram tablets became significantly cheaper again. **3. Inclisiran** DN clarified that the process is being followed rather than seeking feedback as initial decision appears to have been made. GMMMG meeting on Thursday 10th February, letter from JS appealing green status is being considered. It will be discussed there, and will hopefully also address concerns with cost and primary/secondary care with pass-through costs. It was noted that there is a NICE-endorsed AAC pathway for lipid management, and it was asked if there were any plans to have a local pathway as this may be preferred by prescribers. JS noted there is little difference between the pathways. It was also suggested that 'separating' primary and secondary care management of inclisiran may be difficult. It was suggested that as NICE doesn't include local referral pathways, maintaining an MFT (or GM) pathway may be helpful. It was noted that whilst cost is one aspect, patient flow and management is another. Currently, with GMMMG but it may come back to CRG after this, and it may be sensible to bring pathway back to CRG and review in March 2022. **Action**: RDTC to submit these actions to MGSG for approval.
3.0 Formulary and RAG	
3.1	**Formulary Amendments Dec 2021 and Jan 2022** CRG approved the formulary amendments to open for consultation.

	December 2021 Formulary Amendments – No comments January 2022 Formulary Amendments TA758 Solriamfetol No comments, though was mentioned with regards to modafinil discussion. TA599 Sodium zirconium cyclosilicate It was noted that there is an ongoing piece of work to review the RAG status. It was highlighted that the patient access scheme removed as price reduced by AstraZeneca. NG191 Managing COVID-19 It was noted that COVID treatments are currently RED, but prescribing may go out into community (with regards to addition of Sotrovimab). It was noted that there may be issues with delivery to patients in the community, especially in Greater Manchester – if done so under CMDU, problem of single-centre in Manchester, whereas other more rural areas might have multiple centres. **Action:** RDTC to open these decisions for GMMMG consultation as appropriate.
3.2	**Steroid Eye Drops** Mr Leon Au (Consultant ophthalmologist, Manchester Royal Eye Hospital) joined for this discussion. It was noted that this review started in 2020 but had been delayed because of the COVID-19 pandemic. The review was requested due to inconsistencies in the RAG status of steroid eye drops on the formulary at present. For example, among steroid eye drops, dexamethasone and fluorometholone eye drops are RED pending shared care protocol while prednisolone eye drops are effectively GREEN, with no clear rationale behind the difference. Preservative free steroid eye drops currently have a blanket status of GREEN for short term use with no clear guidance on what short term means. These issues can make it difficult to understand which RAG should apply and the RDTC frequently receives queries on this formulary section. This review aims to address these issues and standardise the RAG for steroid eye drops and improve the clarity of this formulary section. Green (Specialist Initiation) is being proposed for all steroid eye drops, and there are plans to develop an accompanying information leaflet. LA explained that this change allows clinic letters to move treatment to primary care, easing the pressure on secondary care clinics and improving access for patients. It was also confirmed this would just be for adults. It was clarified through discussion that the aim is not to pass monitoring requirements onto primary care, but the prescribing responsibilities to enable patients to get medicine easier. Raised intraocular pressure (IOP) and cataracts are main concerns with long-term steroid treatment, and it was suggested that both conditions are those that could be identified by local optician during routine check up. It was explained that even in those on very-long-term steroid eye drops, such as post-transplant surgery, review is typically annually. There was some disagreement on appropriate interval and it was suggested that it may be better to bring the review interval down. It was noted that local opticians may not actually be commissioned for follow-up monitoring of ocular steroid use. It was also highlighted that GPs may be wary of the long-term risks of steroid

	eye drops, and it was suggested that additional support/information may be needed about this and duration of use. It was asked if PIFU would apply for these patients. Mr Au confirmed it would not as PIFU is "in infancy" in eye department, those on steroid eye drops would have regular follow-ups. It has not yet been discussed with GM-wide ophthalmologists; at the moment it has been lead by the Manchester Royal Eye Hospital. It was suggested that feedback from clinicians in other areas across Greater Manchester would be important as part of consultation process, and that the team at the Manchester Royal Eye Hospital behind this request should liaise with colleagues to aid this. Duration of therapy was discussed; SPCs give varying ranges (1-12 weeks). LA clarified that most patients with inflammatory eye conditions receive longer term therapy than the licence would suggest. By the time that patients move to GPs, they have already had weeks-to-months of therapy, so may well be beyond this timeframe already. If any acute problems after treatment started, would be identified by specialist. **Action:** To send out for consultation (with amendments as discussed for clarity)
3.3	**Dacepton (apomorphine)** Dr Paul Cooper (PC) (Northern Care Alliance) present for this discussion, and presented by LO (from RDTC) The group reviewed an application for the addition of Dacepton to the formulary. The application was submitted by MFT but AM confirmed that the request was also supported by SRFT. Dacepton is a brand of apomorphine which is used to treat motor fluctuations in Parkinson's disease. It was highlighted that the main difference between Dacepton and APO-go was the device, though there were also differences in in-use shelf life. It was also clarified that this request is not to replace APO-go on the formulary but to add Dacepton (solution for injection cartridges, and solution for infusion) alongside. Key points include; • Dacepton in-use shelf life is 15 days, compared to 48 hours for APO-go. • Dacepton solution for infusion stability is 7 days, as opposed to "immediately" for APO-go. • Dacepton devices draws up solution automatically. (I.e. it requires less dexterity for use.) • D-mine-pump is milligram based, whereas the APO-go infusion device is millilitre based. The mg based system removes the need for calculation of flow rate. • D-mine-pump has downloadable history. It was suggested that the likely practice based on possible formulary amendment would be new patients start with Dacepton, though those stable on APO-go remain on this product. If approved, the Shared Care Protocol would only need a technical update to add the product. It was also noted that the Shared Care Protocol was due for review 1st December 2021, so the timing of this technical update works well. Current problems with the training process for APO-go (with regards to complexity, need for calculations, etc) and wastage (expired product, from dose calculation/transfer) were noted. It was clarified that the only consumable required for prescribing with Dacepton is the pump reservoir; infusion lines are provided by the manufacturer and do not need prescribed separately. The importance of ensuring the required consumables for each product are clear in the shared care protocol was highlighted. Concern was raised that it may create problems for hospital admissions when staff are used to APO-go devices; likely need to look at retraining staff.

	Approved. It was asked whether this should be equal to APO-go, as alphabetically it would appear below and appear to be a second-choice. However, with benefits, it was suggested we list it non-alphabetically and put Dacepton above APO-go in the list. **This was agreed** **Action**: Decision to go out for consultation. Shared Care Protocol to undergo technical update, and then return to CRG for approval.
3.4	**Tirbanibulin** CRG reviewed an application to add Tirbanibulin (Klisyri®) ointment to the GM formulary as a GREEN item. Tirbanibulin is indicated for the field treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis of the face or scalp in adults. Klisyri® is more expensive; a five-day course of Klisyri® costs £59.00, whereas a 40g package of fluorouracil 5% cream (Efudix®; the current treatment within the GM formulary) is £32.90. (Source: dm+d.) Despite the increased cost, the Tirbanibulin treatment course is a single five-day, once-a-day course, compared to 3-4 weeks of daily use of fluorouracil 5% cream, and may be more tolerable as a result. The application received by CRG referred to the Primary Care Dermatology Society pathway for actinic keratosis. There is a current GM pathway for actinic keratosis treatment in primary care, which only includes 5% fluorouracil cream as a treatment option. It was questioned whether CRG should approve a treatment knowing its position in the pathway is unclear. It was noted that although fluorouracil 5% cream (Efudix®) is the only treatment option in the current GM pathway, there are high rates of prescribing of diclofenac 3% gel (Solaraze®). It was suggested that the pathway needs looking at here as it may not match current practice. It was also noted that Efudix® is used significantly in secondary care, too, so a formulary change (I.e. the addition of Klisyri® as a GREEN option) may cost more than is anticipated based solely on primary care numbers. It was suggested that the application estimate of 200 patients per year was an underestimate of potential patients using Tirbanibulin. It was asked whether community dermatology teams were involved in application process and this was not clear. It was suggested that CRG does not proceed with approval until pathway concerns are resolved. **Decision: Tirbanibulin needs to be considered within the review of the Greater Manchester actinic keratosis pathway.**
3.5	**Bempedoic Acid RAG review** JS explained the background to this request. CRG was informed that a GP pointed out recently that this medicine is in the formulary as “specialist initiation” and not “specialist advice”, and refused to prescribe it on advice alone. It doesn’t need special monitoring, and seems an oversight as JS under impression it was already down as “specialist advice”. CRG agreed to this change to the RAG status (to GREEN (Specialist Advice)). **Decision**: Approved to go to consultation for change to RAG status.
4.0 Pathways and Clinical Guidelines	
	No updates
5.0 Shared care	

5.1	It was noted that with pending ICS changes, there is a bit of uncertainty at the moment and delays with GMMMG processes.

6.0 Work plan and horizon scanning

6.1	**Horizon scanning Dec 2021 and Jan 2022** December 2021—No discussions. January 2021 **1. Sitagliptin Generics** Potential for savings over next year, and this remains a possible April 2022 CRG agenda item. The release of product licences is reassuring as typical time-frame to launch is about six months, so it does look like launch may be planned for September when patent expires. It was asked if generics automatically go onto formulary, and as first choice, or whether it needs discussion and approval. It was clarified that in this case it is a generic medicine, and is often prescribed generically already. It was suggested we schedule this and discuss wider issues of dipeptidyl peptidase-4 inhibitors ('gliptin') swaps. **2. Somatrogon (Ngela®)** In December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion of Ngela®. It was highlighted that CRG may need to consider it for the GM paediatric shared care protocol for growth hormone in due course.
6.2	**MGSG work plan** Received for information.

7.0 AOB

1. NICE TA769: Palforzia for treating peanut allergy in children and young people

It was highlighted that there are potential implications for primary care, and it was noted that there are concerns regarding possible referral increase for peanut allergy treatment. Lack of community allergy service in Manchester noted as a concern. Suggested we wait for TA to appear in formulary amendments (for March 2022 CRG Meeting) and discuss then.

Two pending TAs were identified that might bring about further discussion at CRG:

2. NICE TA: Icosapent Ethyl

Highlighted possible concerns regarding QALY-benefit (with NICE review). TA appraisal consultation currently in progress.

3. NICE TA: Semaglutide for managing overweight and obesity

This TA is in process but it was noted that it is looking like it might be positive. Similarly to liraglutide, would be from a tier 3 or 4 weight management service. No Patient Access Scheme for semaglutide, but cost not clear at present.

Date of next meeting: Tuesday 8th March 2022 12:00-14:00 via Teams