Co-chairs: Robert Hallworth & Dr Peter Budden
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GMMMG Medicines and Guidelines Subgroup
October 25th 2021, 12:00-14:00
via Teams
Minutes

Present:

Name	Title	Organisation	Apr	May	Jun	July	Aug	Sep	Oct
Robert Hallworth	Specialist Cancer Pharmacist	NHSE	A	✓	✓	✓	✓	✓	✓
Dr Pete Budden	GP Prescribing lead	Salford CCG	✓	A	✓	A	A	✓	✓
Petra Brown	Chief Pharmacist	Pennine care NHS FT	✓	✓	✓	A	✓	✓	A
Nigel Dunkerley	Locality Medicines Optimisation Lead	Oldham CCG	A (FT)	✓ (+FT)	✓ (+FT)	✓ (+FT)	✓	✓ (+FT)	FT
Claire Foster/ Lara Shah	Senior Medicines Optimisation Advisor/Deputy MO Lead	MHCC	✓	✓	✓	A (AH)	A (AH)	✓ LS	✓ LS
Jonathan Peacock	Chief Pharmacist	Tameside & Glossop NHS FT	✓	✓	✓	✓	✓	A	✓
Prof. Peter Selby	Consultant Physician	Manchester FT					A	A	A
Anna Swift	Associate Director Medicines Management	Wigan Borough CCG		✓	A	A	✓	A	A
Amanda Fox	Assistant Chief Finance Officer	Oldham CCG	A	✓	✓	✓	A (KR)	✓	✓
Rebecca Demaine	Associate Director Commissioning	Trafford CCG	✓	✓	A	✓	✓	✓	A
Claire Vaughan	Head of Medicines Optimisation	Salford CCG			✓	A	A	A	(TSM)
Paul Buckley	Chief Pharmacist	Stockport FT				✓	✓	A	A
Darren Staniforth	HCD Pharmacist	Manchester FT				✓	A (CO)	✓	✓
Hafsa Sattar	HCD Pharmacist	PANHT				✓	A	SE	SE
Juliet Bell	Senior Clinical Pharmacist	Bury GP Federation					✓	A	A
Andrew Martin	Strategic MO Pharmacist	GM Joint Commissioning	✓	✓	✓	A	✓	✓	✓

		team							
Andrew White	Head of Medicines Optimisation	GM Joint Commissioning team		✓	✓	✓	✓	✓	✓
Sarah Jacobs	Strategic MO Pharmacist	GM Joint Commissioning team				✓	✓	AP	AP
Monica Mason	Head of Prescribing Support	RDTC	✓	✓	✓	✓	A	✓	A
Dan Newsome	Principal pharmacist	RDTC	✓	✓	✓	✓	✓	✓	✓

1. General Business	
	Welcome and apologies (See register above). Robert Hallworth chaired the meeting MGSG lacked representation from commissioning and mental health and was therefore not quorate. The group welcomed Tsz Shan Mak, deputising for CV and Dr Tracey Vell, Dai Roberts and Louise Bond of Health Innovation Manchester in attendance for item 3.4
1.1	**Declarations of interest** None declared
1.2	**Minutes of the MGSG September meeting** The minutes were approved an accurate record of the meeting held on 23rd September 2021
1.3	**Action log review** DN & AW provided an update on action 082101. DN provided feedback on items 042103 and 092101 & 092103
1.4	**Update from October GMMMG and CRG** AW provided the update from October GMMMG to note the discussions on rebates, neutralising antibodies and inclisiran which is on today's agenda. DN informed MGSG of the decision taken at CRG to make all drugs for paediatric cystic fibrosis RED to reflect where these *should* be managed but to recognise that this isn't yet possible. A communication from GMMMG to NHSE is planned to ask for further information on timescales for the repatriation of these and adult transplant medicines. **Action: none required**
2.0 Reduce variation in access to shared care across GM	
2.1	**Update on GM Governance regarding SCP commissioning**

	This is now a standing agenda item to which AW provided a verbal update as part of the action log review.
3.0 Medicines and Guidance	
3.1	**Draft GMMMG Inflammatory Bowel Disease High Cost Drugs (HCDs) Pathway** AP presented an updated version of the GMMMG IBD pathway requesting permission to open for consultation. The major amendments for this update include; incorporating new licensed and NICE-approved products, a statement to the effect that Inflectra and Remsima are the same interchangeable product which was agreed by the HCDSG, the addition of dose-escalated infliximab (out with the NICE TA) and the preference that local MDTs replace the need for IFR for sequential HCD prescribing. Infliximab is licensed for some of the dosing regimens in the pathway but is not routinely funded because this is outside of the NICE TA. It is however, routinely used across GM and supported by a good evidence base, therefore the pathway has been updated to reflect this. Moreover, as there are a number of biosimilars available, the cost implications are low. This is in contrast to ustekinumab dose escalation which is off-label and with high cost impact; this was considered as a separate agenda point. MGSG heard that due to review of the GMEUR service underway, there is a need to reduce the number of IFRs to the point that only truly exceptional cases are expected to be considered from April 2022.This means that IFRs for other types of requests e.g. off-label HCD use (as discussed above) or for patients who reach the end of the commissioned pathway (sequential biologic use), will not be considered and effectively will need an alternative approval route. The recommendation to replace the need for external IFR approval with provider-based MDT is suggesting a local process, managed by clinicians. MGSG recommended that a set of principles are drafted to govern the remit and scope of the MDT groups and that there is some oversight of decisions maintained by a reporting function. It was recognised that this proposed process seeks to find the compromise required to manage the growing numbers of biologics available and mandated through NICE TAs. Allowing for local decision on sequential HCD use would align GM with the RMOC statement on sequential use of biologics (updated May 2020). It was noted that GMMMG did not implement this recommendation at the time of publication. It was acknowledged that this pathway is focused on clinical aspects and deliberately does not include an assurance framework because this is yet to be discussed by GMMMG. MGSG have committed to developing a HCDs assurance reporting structure as soon as the direction and authority from GMMMG is granted. This would include assurance for use of sequential biologics beyond number of routinely commissioned HCDs to ensure value for money principle is achieved. MGSG recognised there has been a shift in the provider-commissioner relationship and that these drugs will be included in the block contracts going forward, therefore a wider discussion on finance implications is required than was previously thought necessary and should involve provider finance as a minimum. MGSG approved the IBD pathway to open for consultation with a minor amendment to the tofacitinib safety warnings following the recent MHRA publication.

3.2	**Ustekinumab dose escalation in IBD – review of existing commissioning statement** As an addition to the IBD pathway, a separate document was presented which updates the commissioning position for GMMMG on the dose escalation of ustekinumab. There is little new published evidence, and that which is available to support this treatment regime is of poor quality and involves relatively low numbers of patients. A manufacturer-sponsored study comparing standard of care against treat-to-target (including 4 weekly escalation) is underway but initial findings do report sufficient detail on efficacy of off-label intervention. The statement has also been updated to include both ulcerative colitis and Crohn's disease. There have been a significant number of IFRs received for this dosing regimen but there is no clearly defined cohort of patients. It was noted that some of these patients would not meet the accepted definition of exceptionality. Due to limited evidence base and significant cost of this intervention, the commissioning statement therefore remains that this treatment is not routinely commissioned. The IBD HCDs working group have had opportunity to comment on the evidence review and commissioning statement. Because this was a technical review and the position has not changed it will not be opened for consultation and will be published to the GMMMG website.
3.3	**GMMMG Project scoping – Narcolepsy with or without cataplexy in adults - regional guideline** This scoping document has been brought to MGSG by MFT following a review of provision of sleep services across GM. There are 2 services in operation, one at SRFT and the other at MFT and there appears to be some inequity in in terms of the treatments patients can access. Patients seen at SRFT for narcolepsy can be offered pitolisant or sodium oxybate if appropriate, whereas if they are seen by the MFT service, these are not routinely commissioned. It appears that Salford CCG has provided local approval for this treatment. **Post meeting note:** Clarification has been provided following the meeting, that all GM's CCG's patients who are referred to the sleep service at SRFT can be offered pitolisant or sodium oxybate. The local approval discussed above and in the meeting papers extends to all associate commissioners of the service. It was proposed that a regional pathway and guideline is developed in line with that which is available in the Pan Mersey region. Clinicians at both MFT and SRFT are keen to be involved making the beginnings of a working group. MGSG approved the preliminary work on the basis that this cannot be put through the GMMMG governance route until at least one of the HCDs pathways currently in development is completed. This is due to resource capacity of the GM support services. There is also a need to adequately capture the financial impact of removing this inequity between services as GM moves to a single ICS commissioner which will be submitted with the draft pathway. **Action:** DS to liaise with interested parties and return a draft pathway to MGSG when there is capacity in the system to consider it.
3.4	**Inclisiran – Implementation of TA733** Dr Tracey Vell, Dai Roberts and Louise Bond were invited to join MGSG for this agenda item which was taken at the top of the agenda after item 2.1. AMart provided a summary of the request from NHSE to implement NICE TA733 and the discussions that took place at GMMMG on 14th October. Tracey Vell offered an explanation of

	the reasons for the rapid implementation and the deviation from normal processes that govern the introduction of novel therapies to a health system. Inclisiran introduction has been modelled on a population health roll out, which has necessitated an innovative approach to providing access. Existing population data on ASCVD points to expected patient numbers in GM of 7-8 patients per practice per year, and a figure of 16844 by end of year 3 was provided by Health Innovation Manchester (HiM). It is claimed that the actual mechanism of prescribing and administration is not dissimilar to existing therapies such as Depo-Provera. It is anticipated that a measure of the implementation of this programme will be included in the PCN DES from April 2022. Novartis have committed to maintaining inclisiran at its current price to the NHS, which is subject to a confidential agreement. The pricing structure for primary care as detailed in the accompanying paper is in place for 3 years, after which NHSE will engage with the future ICB systems and / or PCNs to determine the ongoing reimbursement arrangements. TV stated that ICS finance leads have been approached and have agreed to the funding arrangements via a top slice of primary care budgets. Unfortunately no further information was available regarding who and what had been approved in GM. MGSG has committed to obtaining more detail on this point which has important implications for the governance of new medicines. MGSG heard that the SPIRIT trial, currently ongoing in GM, was designed to provide the implementation guidance to support the roll-out, but has been delayed by COVID and will not report any mid-trial data until December 2021. It was noted that this study continues to enrol new participants and is aiming for around 900 patients in total. It was raised that inclisiran is a new therapy and is being implemented in such a way and at a pace that is likely to make many in primary care concerned. The lack of outcome data and use of a surrogate marker of LDL-C levels was pointed out. MGSG asked how real-world population health outcomes such as MI and CVD deaths were going to be collected to justify the product licence and NICE approval. HiM pointed to a number of ongoing studies looking at just this, including the aforementioned ORION study. Primary care is understandably anxious about the further workload that this directive places on them and that the small margins per dose is insufficient remuneration for this. MGSG heard that consultation with the BMA and RCGP had determined that there is little additional impact expected from the introduction of inclisiran. MGSG members expressed concern that the financial pressures all NHS organisations are under may seem incompatible with the introduction of an expensive new and unproven therapy. Comments from secondary care communicated a lack of engagement with specialist lipidologists who remain keen to use the drug in their clinical practice but feel that the pricing structure prevents this and therefore precludes them from using a potentially beneficial drug. They also raised concerns about the long-term safety profile of the drug. It was suggested that an FP10 prescription route could be used from clinic or a communication to the GP for eligible patients would be appropriate. TV and DR were asked about what support was planned for primary care to manage the implementation of inclisiran within the 30 day period specified by NICE. MGSG heard an updated lipid pathway is being published on 14th November which will place inclisiran as an option following maximum tolerated statin therapy. At this point, the prescriber has the option to choose inclisiran, ezetimibe or refer for PCSK9-i therapy (if eligible) with or without a statin. Support appears to be being offered to practice and PCN groups on an opt-in basis, led by Paul Jackson as the clinical lead. When it was suggested that this may not be in keeping with a CCG's statutory requirement to make the drug available to all patients this issue was not

	answered by HiM representatives. HiM stated that that MO briefing pack contains the necessary information to enable prescribers to initiate inclisiran, and that they are willing to work with all practices and PCNs to support them with this programme. GMMMG will remain keen to understand if the case finding tool is yet available and which GP clinical systems it is compatible with. MGSG were left with further questions regarding the funding, assurance of meeting NICE TA requirements, long term effect and measuring outcomes and secondary / tertiary care access to the drug at a cost effective price. RDTC agreed to collate these from the minutes and submit to HiM for further details and a response to the specific points. **Action: RDTC to collate questions for HiM and request further information prior to GMMMG in November.**
3.5	**GM Antimicrobial Guidelines Update – V9.2** Updates to this guideline have been made based on NG198; acne vulgaris, NG199; Clostridioides Difficile and updated wording to reflect the MHRA safety update advice regarding borax or boric acid buffer contained in chloramphenicol eye drops. MGSG approved the updates for publishing to the GMMMG website. AW commended the majority of GM organisations for meeting their AMS targets to date, but accepted that COVID may have limited patient access to clinicians and as a result caused a decrease in prescribing rates of antibiotics.
4.0 GMMMG Governance and BAU	
4.1	**CRG decisions for MGSG consideration and approval** All decisions were approved. MGSG will communicate to GMMMG that the financial impact of TA715 will be collected as part of the development of the moderate RA pathway. To support this it was agreed a Blueteq form be created to gauge the actual levels of uptake for this group of patients. **Action: DS to provide an outline of an appropriate Blueteq form for MGSG approval.**
4.2	**Blueteq forms – Bimekizumab for psoriasis** MGSG accepted the forms for immediate use noting that this product has a 30-day NICE TA and is not yet included on the psoriasis HCD pathway.
4.3	**RDTC Monthly Horizon scanning: October** MGSG received the horizon scanning document from October and noted: • Trimbow DPI is favoured for use by the COPD clinical working group and is being written into the COPD pathway. • relugolix / estradiol / norethisterone (Ryeqo®) is being reviewed by NICE but a TA is not expected until June 2022. Does this need a GM position prior to that? • A new product for actinic keratoses; tirbanibulin has been launched and initial thoughts are its place in therapy may be limited. Await formulary request. **Action: None**

4.4	**MGSG work plan 2020-21** For information **Action: None required**
4.5	**National and regional updates** DN acknowledged that RMOC shared care working group were very positive towards the GMMMG shared care patient information leaflet and agreed to include it in their national consultation documents. **Action:** None required
5.0 AOB None raised	
Date of next meeting: 22nd November 2021 12:00-14:00 via Teams	