Chair: Charlotte Skitterall, Joint Chief Pharmacist, MFT
Vice Chair: Claire Vaughan, Head of Medicines Optimisation, Salford CCG
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HIGH COST DRUGS SUBGROUP

Wednesday 22nd August 2018, 10am until 12 noon.
St James House, Salford

Minutes

1. General Business	
1.1	Welcome and apologies (See register in appendix 1) Apologies as per register were noted. Professor Richard Warren attended the meeting to provide specialist opinion for items 2.5 and 2.6.
1.2	**Conflicts of Interest** AM declared that he had attended **an advisory board for Amgen** in July 2018. The Chair along with members of the group expressed concerns with members of GMMMG attending advisory boards or receiving personal payments from Pharma for work which was also being undertaken by GMMMG. SJ explained that GMSS had implemented a system of assurance which meant that any individual undertaking paid work would not then be involved in that GMMMG work stream, so as not to pose a conflict. It was agreed that AM would leave the room for item 2.1. There was further discussion around the declarations of interest for working groups supported by GMMMG. It was explained that these individuals were not all GMMMG members but were normally GM clinicians with specialist knowledge in the treatment are under discussion, with a GMMMG subgroup member supporting. The GMMMG member would be responsible for ensuring that DoI were requested for submission to the RDTC to be held on the register, and should be discussed by the subgroup during scoping of the pathway development and at approval.
1.3	**1. Minutes** The draft minutes from the June meeting (no July meeting) were agreed as accurate following minor amendment. **Action: Publish on GMMMG website following CSB**
1.4	**Actions and Matters arising** Actions recorded from the previous meetings were noted and ongoing issues

	discussed. There was discussion around Blueteq and the need for this system to provide data beyond that currently provided in the format of the challenge reports, which were considered to be of limited value. The need for Blueteq data to provide HCDSG with reports demonstrating GM HCD NICE compliance e.g. the number of patients on more than the recommended sequential biologic regimes, was discussed and it was agreed that BG would lead on the further development of these reports with the support of some HCDSG members (SJ to confirm with those involved). **Action: GMSS (SJ, BG) to lead on this work and return to a future HCDSG meeting**
1.5	**Review of GMMMG Subgroups Terms of Reference** The terms of reference (ToR) for the GMMMG subgroups are undergoing review; all members were asked to submit comments to MM within the following two weeks. Following comment by all three subgroups the revised ToR would be returned for approval. **Action: Members to submit proposed changes and comments to MM within the next two weeks.**
2. Medicines Optimisation	
2.1	**Progress report on GM biosimilar adalimumab project – July/August 2018** HCDSG members were provided with an update on the GM biosimilar adalimumab project from the working group and noted that it is progressing as per the project plan. Some new issues had been identified and recorded in the project's issue and risk register, which the group discussed, the project assurance is now reported via the trusts' assurance checklist spreadsheet, and copies of both documents were presented to HCDSG for information and discussion. HCDSG understood that as both are living documents any new significant developments will be reported during the meeting. It was suggested that both documents need to be validated by the chief pharmacists before being disseminated, and acknowledged that this would add complexity to reporting. At this point the group discussed the various levels of progress made with business cases, and reported on further action being taken. As there had been no HCDSG meeting in July, an interim report had been disseminated by email, since then the working group had met on the 1st August and HCDSG discussed the progress made. HCDSG were informed that the next working group meeting will include presentations from two of the homecare providers to discuss transition. The working group also suggested an engagement event for the biosimilar adalimumab suppliers post Humira® patent expiry. HCDSG supported an open meeting with representatives from all adalimumab biosimilar companies to present their products to representatives from GM Providers and commissioners including clinicians, a date was discussed and venues requested, to be confirmed following this meeting. Patient communication tools not available via the national work streams are being produced on behalf of the working group. AP informed the group that one of the biosimilar suppliers presented a local discount deal to GM NHS providers. It was understood that such deals can jeopardise national and regional tendering processes and should not be upheld. GH was not present at the meeting, but it was understood that the position of regional procurement not to

	enter new contracts with Pharma effective beyond patent expiry. It was agreed that the Chief Pharmacists would communicate this to GM Trusts at their upcoming meeting, and that a teleconference would be arranged in the coming weeks to discuss this issue, and to enable the working group to provide any further updates. It was agreed that criteria and process for selection of the "best value" biosimilar adalimumab be agreed at the Sept HCDSG meeting. It is the role of HCDSG to undertake regular monitoring of biosimilar uptake via trusts high cost drug data submissions reported by GMSS. It was acknowledged that there is around 6 weeks delay in reporting and if the adalimumab biosimilar uptake commences in December the first results will be available in February. CS communicated the request from HSCP for a GM adalimumab saving figure to be shared. It was recognised that based on the predicted volume of use of adalimumab in GM and historic biosimilar prices the potential maximum saving was estimated to be around £7M, however this was a crude figure based on all patients switching per annum. CV highlighted the KPI targets and queried whether this had been included in all commissioning interests, and whether this should be followed up by the commissioners through contract monitoring. Feedback from national work streams confirmed no progress with regards to the procurement strategy, and concern was raised on potential stalling of the tender process, e.g. due to a potential legal challenge by one of the participants. The expected date for CMU contract availability for adalimumab remains unchanged (December 2018). There is apprehension about timing of this switch (festive period, winter pressure, increased rate of infections). A statement is expected from the UK government regarding medicines stock in the UK after Brexit, however, stocks may also be affected by rapid uptake across the country following the launch. NHSE released their toolkit for trusts and commissioners as well as some patient communication tools. Further documents are expected form the patient communication group in due course. NHSE's toolkit acknowledged but not providing much new over what has already been planned for locally. Chief pharmacists explained that they had raised the issue of clinician engagement with NHSE Chief Pharmaceutical Officer (KR) during his recent visit, CS agreed to contact KR to seek a response. **Action: A telecon will be arranged to carry forward the actions agreed at the August meeting, prior to the September meeting. An assurance report to CSB stating the positive and negative assurances identified to date, a holding statement to support the managed entry of adalimumab biosimilar and a risk register (to be validated by HCDSG members), are also to be supplied** *Post meeting note: The telecon was not held but instead discussions were taken with key members by email.*
2.2	**Biosimilar Assurance Report** There was short discussion around the report recently submitted to CSB to provide assurance on uptake of biosimilars across GM. It was recognized that the report could benefit from further development and HCDSG were asked to direct the authors to specifics that are required from this report, also the frequency and route of reporting.

	It was accepted that the paper should hold primary and secondary care to account and that the report be further developed to show both commissioner and provider positions. It was also requested that Chief Pharmacists provide GMSS with the information requested i.e. why some biosimilar switches e.g. those with a red status had not happened if this information is to be used to further shape this report. **Action: AM to develop this report further and submit to HCDSG for pre-approval prior to CSB submission.**
2.3	**RMOC Free of Charge Medicines Policy** The group noted that the Free of Charge Medicines policy which had been developed through NHSE MO CRG with the support of the GMMMG HCDSG during the last twelve months had been ratified through the RMOC for adoption as local policy. The policy should ensure that only free of charge medicines schemes that have a positive clinical impact on patients should be considered, and should reduce health inequalities by ensuring that free of charge medicines schemes do not provide medicines only to a cohort of patients in a single GM Trust. The group acknowledged that w**hilst F**OC schemes may appear to offer the potential for a short-term saving in the cost of the medicine, the need for supporting infrastructure and ongoing monitoring of the medicine could outweigh the benefits anticipated. The policy should ensure that FOC schemes are assessed for any potential financial implications including financial, workforce and operational risks. The group noted that this policy had not followed the GM development process as it was not a GMMMG policy but rather a national one. HCDSG recommended this policy be accepted for adoption locally, no further consultation was required but CSB approval should be sought. **Action: MM to communicate the recommendation of this policy for local adoption across GM to CSB, and to add to the GMMMG website.**
2.4	**PBRex Summary Spend Reports: Demonstration of DRAFT summary spend reports on the BI platform** ***This item was deferred to a later date***
2.5	**Dupilumab recommendation** The group were updated on the publication of NICE TA534 (Dupilumab for treating moderate to severe atopic dermatitis) at the start of August 2018, and noted that this was a “30 day TA” of a drug previously available via on the ***Early Access to Medicines Scheme***. GM CCGs fund positive TAs from day one but are seeking estimates of patient numbers in order to assess financial implications. Prior to issue of the TA, the estimated cost implication was a pressure of £1.38 million annually across GM based on 84 eligible patients from a population of 2.8 million. SRFT have confirmed they are already aware of about 50 patients whom they believe would benefit from this drug, and that additional specialist clinics were being considered. The

	group discussed the initiation criteria specified by NICE ("recommended as an option for treating moderate to severe atopic dermatitis in adults"), and queried the lack of a defined measure for the extent of the disease presented. Prof Richard Warren attended the meeting to provide a specialist opinion on this agent and explained that most of these patients would be seen at SRFT but that there may be some clinicians wishing to use this agent at additional clinics across GM. He agreed that there was a need for a scoring system for condition severity to be included in the criteria for prescribing, but that this may be difficult to correlate across GM initially, and following an initial 6 month period of monitoring of prescribing these criteria may require review. The group agreed that a Blueteq form be developed which would record the EASI and DQLI scores for the patient, and that prescribing of dupilumab at SRFT would be conditional on the use of this Blueteq form. Commissioner representatives present agreed that commissioners wanted assurance that this agent was being prescribed in line with NICE, and would enable the HCDSG to monitor the whether NICE's continuation of treatment criteria were being met. It was agreed that this data would be reviewed in six months and that this review would be clinician supported. **Action: AM to return any additional cost and commissioning implications to the September HCDSG meeting, and develop a Blueteq form for use as described above. MM to add this item to the work plan for a six monthly review. The criteria for use should be communicated to FMESG for formulary inclusion.**
2.6	**Proposal around increasing dosage of certolizumab in PsA** The group noted submission of a paper asking for consideration of a request that a cohort of patients with Psoriatic Arthritis – both joint and skin disease – be considered for a dose increase without the need for IFR submissions with the cost of the increased dose being met by the manufacturer. However it was noted that this paper had not yet been through the SRFT approval process, should not have been received into HCDSG at this stage and would not be considered at this meeting. It was also noted that if this practice is in line with the FOC policy which is to be adopted across GM, then it may not necessarily need to come to HCDSG for approval. **Action: No further action at this stage**
2.7	**Anti-monoclonal antibodies for migraine prevention: scoping** There was insufficient time available for discussion of this item; however it was noted that a working group is being formed to take these discussions forward in light of the delayed NICE timescale, and HCDSG will receive an update in due course. **Action: Update from the working group to return to HCDSG in due course.**
3. Horizon scanning and work planning	
3.1	**RDTC MHSD (includes MHRA DSU links) (July and August 2018) and work plan** This item was deferred to the next meeting, it was agreed that the Chair and Vice chair

	would look to set the agenda for the next meeting, noting the capacity of the meeting to accommodate lengthy adalimumab biosimilar discussions.

4. Communication from other groups

	• GM HCD optimisation network – no update • Medicines Optimisation Clinical Reference Group – nothing to update • HIM – CS due to meet with HIM and will update HCDSG at the next meeting • Chief Pharmacists – updates regarding adalimumab discussed above • RMOC – MM to email SB to request that the FOC reflect the involvement of GMMMG HCDSG

5. AOB

	Nil

Date of next meeting: Wednesday 26th September 2018. Community Room 1, Pendleton Gateway, Salford

Attendee	F	M	A	M	J	J	A	S	O	N	J
Charlotte Skitterall Chief Pharmacist MFT		✓	✓	✓	✓		✓				
Danielle Timoney Lead Pharmacist Medicines Management MFT		A	✓	✓	✓		✓				
Steve Simpson Chief Pharmacist Bolton Trust		✓	✓	A	✓		✓				
Paul Buckley Chief Pharmacist Stockport Trust		A	A	A	✓		✓				
Darren Staniforth HCD Pharmacist MFT		A	✓	✓	✓		✓				
Selwa Elrouby or Andrea Marrosu HCD pharmacist or MI pharmacist SRFT		✓ SE	✓ AM	✓ AM	✓ AM		A				
Robert Elsey Specialist Pharmacist PAT		✓	✓	✓	✓		✓				
Claire Vaughan Head of MO Salford CCG		✓	✓	✓	✓		✓				
Jeanette Tilstone Head of MO Bury CCG		A	✓	✓	✓		✓				
Susan McKernan Senior MO Adviser North Manchester CCG		A ✓ KL	✓	✓	✓		✓				
Jole Hannan CCG Interface Pharmacist Bolton CCG		A	A	✓	A		✓				
David Dolman Deputy Chief Finance Officer Stockport CCGs		A	A	A	✓		A				
Glenn Harley NW Procurement lead NW		✓	A	✓	✓		A				
Connie Chen GP Manchester CCG		A	✓	A	A		✓				
Consultant rheumatologist (Therese Brammah, Sahena Haque, Louise Mercer, Surabhi Wig (Bolton)or Charlie Filer)		✓ SH	✓ SW	✓ CF	✓ CF		A				
Sarah Jacobs Head of MO GM Shared Service		✓	✓	✓	✓		✓				

Andrew Martin Strategic Medicines Optimisation Pharmacist GM Shared Service		✓	✓	✓	✓		✓				
Anna Pracz Medicines optimisation pharmacist GM Shared Service		✓	✓	✓	✓		✓				
Brian Galea Systems Administrator GM Shared Service		A	A	A	A		✓				
Monica Mason Head of Prescribing Support RDTC		✓	✓	✓	✓		✓				