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

Wednesday 27th June 2018, 10am until 12 noon.
Community Room 1, Pendleton gateway, Salford

Minutes

1. General Business	
1.1	Welcome and apologies (See register in appendix 1) Apologies as per register were noted.
1.2	**Conflicts of Interest** Nil
1.3	**Minutes** The draft minutes from the May meeting were agreed as accurate and pending some minor changes to section 2.1 will be published to the GMMMG website. **Action: Publish on GMMMG website following CSB**
1.4	**Actions and Matters arising** The group considered the action log the majority of which was to be considered on this agenda, but noted that work is ongoing to prepare a dupilumab position statement however has been delayed due to a delay in communication from the Trust specialists.
2. Medicines Optimisation	
2.1	**Progress report on GM biosimilar adalimumab project – June 2018** A progress report from the working group was presented to HCDSG by GMSS. The author asked for comments on the format of the report, it was commented that this topic develops so quickly that often the progress report is outdated by the time it reaches HCDSG. It was requested that where a major issue develops or if action is required from Trusts or Commissioners in the interim that this items be escalated to those concerned and that any actions taken or recommendation made be added as an interim report. There was some concern that some of the risks were not being communicated quickly enough to Trusts, and that monitoring against the implementation plan was not being undertaken. The working group reps responded that at this stage HCDSG hadn't actually agreed that monitoring at organisation level would be undertaken, but that a tracker was in development, and in addition an RMOC

	briefing was expected soon. HCDSG members commented that they felt that the RMOC was yet to deliver, and that GM was probably further ahead and as such GM should measure itself against its implementation plan. It was agreed that AP would provide a tracker which highlight Trusts progress to date using a traffic light system, this would return to the next meeting, an exception report would be included within the progress report. It was recognised that this additional information would support Trusts in engaging with clinicians, and would provide a level of benchmarking. It was agreed that this information should be provided in a pictorial format where possible. It was requested that information be included summarising business plans being developed internally by Trusts versus those being developed by Commissioners. The group felt it would be of benefit to have a GM overview of the level of investment between the different Trusts and Commissioners. AP explained that the baseline scoping had captured some of this, but it was difficult to differentiate NHSE vs CCG commissioned uses. The group also commented that "lessons learnt" would be useful e.g. the benefit of a pharmacist or technician investment. There was comment from some around the table of the benefits experienced to date from a specialist pharmacist and technician team. The group considered the risk register summary within the update paper, which highlighted risks e.g. clinical reticence, poor communication between Trust directorates and clinicians. Members explained that some clinicians are reporting that they cannot have an opinion on using biosimilar adalimumab without knowledge of the products and how they may differ from the originator product. There had also been query raised regarding the position of the originator product if it was to reduce its price to match the biosimilar products, although it was acknowledged that anti-competitive laws should prevent a change in list price, further clarification was required around this possibility. It was agreed that the concerns being raised by GM clinicians were very likely to be raised across the country and that as there should be no difference in the evidence being considered NHSE should be addressing these once and for all. It was also agreed that NHSE should be engaging with clinicians via their Royal Colleges and Representative bodies to offer reassurance. It was also agreed that a newsletter be produced by the working group for distribution to clinicians to provide as much information as possible at this stage. The working group leads fed back to HCDSG on their meeting with Abbvie, and explained that Abbvie were keen to understand the GM appetite to continue to use their product should the price decrease. They also confirmed that there would be no 80mg preparation launched. The leads confirmed their intention to use the best value product. The participation of independent providers in the biosimilar adalimumab project was re-discussed and the HCDSG upheld their position that private providers are outside of the project's remit, whether they exclusively treat NHS patients or not. This is because of confidentiality of information dealt with within project's scope, e.g. procurement. Furthermore, it is up to the commissioner to consider contractual arrangements, inclusive of standards of care and delivery of medicines with the contracted provider. There was some discussion on the GM target for uptake of the adalimumab biosimilar. It was recognised that there may need to be a reminder that uptake will not commence

	from day 1 of the biosimilar product being launched, as this will be the start of the tendering process which will take approximately six weeks, and that whilst GM would still achieve the targets set that the timeline for this may not be as quickly as first anticipated. It was also recognised that different Trusts would be ready to switch at different times, and that early adopters could provide a confidence to those who were more reluctant. It was reported that a recent presentation to the GM Commissioners had indicated that savings would be generated from October 2018, CV agreed to contact MO'D to clarify the fact that the start date for switching would not be before December 2018, and to ask that this be communicated to all organisations. CS asked that SJ share the date of the update meeting scheduled between SJ and Richard Preece at HSCP so that the HCDSG Chair or Vice Chair could attend.
2.2	**Biosimilar Assurance Report** A report on the current status of biosimilar uptake across GM was considered by the group. An improvement in biosimilar uptake was expected following the approval and adoption of the GM gain share principles and biosimilar uptake agreement at the start of the year, this report demonstrated an improvement in biosimilar uptake and demonstrated that a number of local health economies are now working together to improve uptake and maximize potential savings. However, it also showed that some localities have not engaged with this exercise and HCDSG members agreed that this should now be escalated to the Clinical Standards Board. The report estimated that the potential lost opportunity appears to be around £50k per month across GM although this is difficult to calculate accurately as there are many additional layers to the calculation of savings that add to the complexity (e.g. biosimilar product mix, Trust service fees, existing homecare arrangements, gainshare agreements.) and so the group were reminded that the numbers presented within the report may not be fully realisable. However the lack of engagement within some organisations was of particular concern given the upcoming arrival of biosimilar adalimumab, and that this lack of engagement meant that Trusts may not be undertaking the necessary operations to review and increase their capacity to support greater use of biosimilars and particularly in preparation for the introduction of biosimilar adalimumab. It was agreed that this report be submitted directly to AGG in order that commissioners be made aware of the current positions across GM, as CSB would not be meeting again until August. **Action:** AM to submit report to MO'D following this meeting
2.3	**GM Biologics pathway for psoriasis** An updated version of the GMMMG biologics for psoriasis pathway had been undertaken to incorporate brodalumab as per NICE TA511, and was presented to the group. The commissioning implications remain unaffected by this inclusion as the number of available treatment options remains unchanged. However the group discussed the implications for Trusts other than SRFT and whether this had been considered? There was a call that the pathway needed to attempt to position the treatment options available, rather than just listing them all. Whilst it was recognised that many of agents had a positive NICE TA, there was still a need for the pathway to support the appropriate number of treatment options received by the patient. Some

	patients are known to receive 5th or 6th option biologics, and there was query as to whether this is appropriate both in terms of efficacy and cost. Whilst it was recognised that clinicians and patients may have exhausted all other options, it was felt that this was not necessarily a satisfactory reason for extended sequential use of these costly agents. It was agreed that the evidence base for sequential use of fifth and sixth line agents be reviewed by the RDTC to return to the HCDSG in the near future. It was recognised that additional information may be required from the registries to provide the assurance to this treatment as it may be unobtainable from any other source. It was confirmed that a full review of the pathway is being undertaken, and a GM wide consultation will be opened to enable all stakeholders to comment. SJ, CV and AM are leading a working group to review the psoriasis pathway and will return this review to the HCDSG once a first draft is ready. **Action: RDTC to review the evidence for fifth and sixth line sequential use biologics in psoriasis. Working group to undertake a full review of the psoriasis pathway as per GMMMG process.**
2.4	**GMMMG pathway adherence and IFR submissions** A paper from GMSS had been prepared in response to concern from some GM CCGs who felt that they are receiving an increased number of individual funding requests (IFRs) for sequential use biologics that exceed the number of treatment options allowed for the GMMMG biologics pathways. The paper used Blueteq data to report that since August 2017 there had been 23 IFRs for sequential use biologics, 22 of which had been approved by the IFR panel. It also reported that using SLAM-HCD data 112 patients out of 186 on >2 biologics had an identifiable diagnosis, 21 out of 112 patients appeared to have more biologics than allowed in the relevant GMMMG pathway, 1 out of these 21 patients had an IFR for sequential use of a biologic. 74 patients had no identifiable diagnosis and therefore could potentially have exceeded the allowed number of biologics for their condition. The paper concluded that HCD-Blueteq system use in all Trusts would enable the complete analysis of HCD data. It also raised the issue that IFRs are not always submitted when the number of treatment options has been exhausted. The paper proposed a number of actions that were discussed by HCDSG, namely that CCG contracting teams should ensure all Trusts use Blueteq or an equivalent system wherever a GMMMG pathway has a monitored approval process in place, and that the IFR process should be followed in all instances i.e. including awaiting approval before the drug is issued to the patient. The paper also asked that all clinicians should be aware of the maximum number of biologics that can be used before an IFR should be submitted. The group asked who is going to liaise with clinicians to ensure this, and that clinicians don't necessarily complete the Blueteq forms themselves. The group also recognised that there is a cohort of patients who require treatment beyond commissioned pathways, but should not necessarily be considered via the IFR route, and that the cost efficacy of 5th and 6th line treatment options should be evaluated. It was commented that the paper presented did not highlight this information, and also did not identify the "problem" areas, and that there needs to be a visibility across GM of the IFRs coming into the

	system. HCDSG recognised that there was a need to measure the variation in IFR funding between CCGs, and also variation in clinician pathway deviation. GMSS are asked to investigate the inconsistencies between IFR panels across GM, and to seek standards for commissioning beyond pathways from the EUR team. It should be the case that if a treatment is agreed out with the current pathway that the outcomes should be reported back into the system. It was also agreed that the use and outcomes of 5th and 6th line treatments for psoriasis be evaluated with the help of the RDTC. This information would then be used to ascertain whether an extension to the current pathway was warranted. **Action: GMSS to investigate the variation in IFR approvals between GM CCGs, to identify the areas for action to improve IFR equity, to liaise with the EUR team regarding the standards which should be adopted when treatment extends beyond the commissioned pathway, to identify those organisations which are allowing treatment without IFR submission.** **RDTC to evaluate the use of 5th and 6th line treatments for psoriasis**
2.5	**Commissioner assurances** HCDSG considered a paper summarising discussions from the HCD commissioner assurance meeting (attended by CCG medicines optimisation leads, contracting teams and finance representatives) to discuss the current approach to HCD contract inclusions and assurances. Discussions included plans for development of 2019/20 commissioner intentions, process for contract inclusion and reporting to other GM groups and HCD assurances – areas for development. It was suggested that GM CCGs and providers had prioritised similar areas for HCD contract inclusion, such as Hackett compliance and uptake of biosimilars, although the detail of the contract inclusions and progress towards full achievement/implementation was variable. It was recognised that a consistent commissioner approach would help to reduce variation and standardise HCD management across GM. However, it was also recognised that this may not always be possible and there would likely be local variances depending on the trust baseline position, infrastructure and resources. The group noted that the 2019/20 contracting round starts in October 2018 the commissioning intentions would need to be agreed by the end of September. It was agreed that there was a need to better engage Providers in this process, and that the HCD commissioner assurance group would meet again prior to the contracting rounds, with support from GMSS. The GMSS contracting teams are undertaking a baseline review of HCD contract inclusions, and a review and update previous GM commissioning intentions had been agreed. These will be shared with GM medicines optimisation leads initially; thereafter a wider consultation would include GM chief pharmacists, GMMMG subgroups and Provider contracting leads. The need to improve communication between contracting teams and medicines

	optimisation leads/HCDSG was briefly discussed, it was recognised that the outputs of the HCDSG should be incorporated into contracts and to give contracting teams some visibility of work being undertaken. It was noted that CSB is currently working to improve this reporting structure, in line with changes being made up the reporting structure. It was recognised by the assurance group that HCDSG had made significant progress supporting GMSS to develop HCD reporting reports. The assurance group had discussed further areas for development, recognising HCDSG discussions around NICE/GMMMG pathway compliance, EUR and IFRs, biosimilars and gainshare reporting, CMU contract pricing. Whilst it was agreed that the majority of the discussions that had been undertaken by this assurance group were covered by the function of HCDSG, it was accepted that the assurance group could support HCDSG in its operation. **Action: HCDSG members attending the assurance group to provide a regular update to HCDSG, and vice versa.**
3. Horizon scanning and work planning	
3.1	**RDTC MHSD (includes MHRA DSU links) (June 2018) and work plan** These documents were noted and would be used to update the work plan accordingly.
4. Communication from other groups	
	• GM HCD optimisation network • Medicines Optimisation Clinical Reference Group • HIM • Chief Pharmacists • RMOC Updates from these groups were noted, it was agreed that RMOC be contacted to consider items identified by the adalimumab biosimilar working group that could warrant regional or national direction.
5. AOB	
	Nil

Date of next meeting: Wednesday 25th July 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 Deputy Director of HCD Pharmacist 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						
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	✓						
Glenn Harley NW Procurement lead NW		✓	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						
Sarah Jacobs Strategic medicines optimisation pharmacist 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 Principal pharmacist RDTC		✓	✓	✓	✓						