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 25th April 2018, 10am until 12 noon
Community Room 1, Pendleton Gateway, Salford.

Draft 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	**1. Minutes** Some amendments were requested to the minutes around the adalimumab working group, these were discussed and some changes were agreed, although it was confirmed that the group would meet monthly as per the minutes and not bi-monthly, after which the minutes were agreed as accurate. **Action: MM to upload to the GMMMG website**
1.4	**Actions and Matters arising** The outstanding actions not included on this agenda were noted by the group. • It was agreed that the invitation to the registry holders to attend HCDSG would be picked up by the adalimumab working group in due course, with an anticipated attendance in the autumn. • The GM wide optimum management of biologics: CS updated the group on the work of the GM HCD optimisation network. Permission would be sought to share this email with HCDSG for information. This included a summary of the progress of local projects being undertaken, it was commented that this sort of report would be useful for HCDSG, whilst it was recognised that HCDSG was now receiving regular reports on the adalimumab project, there was still a lack of reporting on other HCDs. GMSS undertake other HCD work and it was queried whether this could be highlighted to HCDSG. • Dupilumab for dermatitis: This item was on hold in light of the fact that NICE have recently issued a draft NICE technology appraisal stating that dupilumab would not be recommended for dermatitis due to the high QALY threshold. HCDSG will await further publication from NICE before deciding whether its recommendation is necessary. AM commented that specialists were keen to

	start patients on this treatment, and that we would watch to see if the manufacturer amended their cost so that an acceptable QALY was reached. • This item was to remain open whilst SMcK communicated with CV. It was noted that a NICE TA was due to be published in June, however currently there was no additional treatment opportunity as a fifth line would only be available via IFR.
2. Medicines Optimisation	
2.1	**Progress report (April 2018): Adalimumab implementation plan** GMSS presented a paper to update HCDSG on the progress of the GM biosimilar adalimumab project since the last update (verbal) provided at HCDSG in March 2018. The paper asked HCDSG to • Agree on the format of reporting and risk escalation to CSB. • Agree the TOR of the working group. • Discuss identified risks. • Discuss participation of independent providers. • Agree commissioner representative for the working group. The group noted from the report that the GM biosimilar adalimumab project was approved by the GM Clinical Standards Board on 12.04.18, and that the project is continuing as per plan without significant variation. GMSS explained that the main focus remains on ensuring efficient and standardised communication between the stakeholders and supporting individual trusts with preparation for implementation. They explained that the scoping for baseline information is underway. The GM biosimilar adalimumab working group had met in April 2018 and the terms of reference had been agreed, with the membership being extended to include clinical representatives from each specialty including nursing and medical. The group commented on this membership, in particular the lack of dermatology specialist pharmacist, the need for an additional commissioner representative, to which SMcK volunteered to attend and SJ agreed to email the leads to ask for a further additional commissioner representative also, and the lack of a patient representative. There was query raised as to the attendance of independent providers at the working group, it was agreed that the representation should come from the CCG responsible for procuring the independent provider and not the provider itself. The working group was asked to scope the private providers of adalimumab across GM, and to return this information to HCDSG as appropriate. The initial risk assessment has been performed and results recorded in the risk register. The risk register will provide the basis for regular updates to HCDSG. Most of the strategic risks relate to procurement and homecare, these are ongoing and unlikely to be resolved until closer to the Humira patent expiry date. These longstanding limitations to the project were acknowledged by the working group and the HCDSG. The operational risks identified at this stage include capacity and resources at individual trusts, effective communication and cascading information to individual staff within specialties. The group queried how they will gain assurance as to the progress of each Trust;

	GMSS responded that the risk register will provide this assurance. Concerns were raised that HCDSG need to see detail beyond the risk register i.e. operational plans, GMSS explained that the working group will oversee the operational aspect of this project, and that the detailed operational plans will be available via the BI Tool, where individuals could update the plans as necessary. HCDSG needs to maintain a strategic role, however in order to maintain an oversight on the working group a formal report should be prepared for HCDSG which could also be communicated to CSB and AGG on a regular basis, similar to that prepared and shared by the GM HCD Optimisation network. Discussions moved on to the necessary communications to be undertaken between Provider Directors of Finance and CCG finance, it was felt that there was a lack of drive from the CCGs to the Providers to support the opportunities that could be gained from biosimilar adalimumab. Additionally it was also felt by some that CCGs need to take greater ownership from other biosimilar switches e.g. Benepali/etanercept also, and that the lack of gain due to previous inefficiencies in switching could not be repeated. For this reason HCDSG need to drive this work forward on a GM level, but to do this the group need to be presented with a project plan built on the operational plans of the working group, in order to provide the HCDSG with sufficient information to drive forward the GM biosimilar strategy. Concerns were raised again around the level of GMMMG communication with Providers. With regard the adalimumab biosimilar implementation GMSS explained that there was a representative from every Trust on the working group, however it was agreed that all GM chief pharmacists needed to ensure that this communication was being relayed to their organisations, but also that Trust medical directors needed to be engaged with this work. Trusts had expressed concern that the resource necessary to ensure clear communication and engagement with clinicians regarding adalimumab biosimilar had been underestimated, and that resource would need to be secured in the near future in order that pharmacy could work to counter the messages being delivered by the originator manufacturers concerning biosimilar switches. The group agreed that if sufficient resource and time was not invested in communication with clinicians then this work would be very limited in its success. The conversation concluded with an agreement from GMSS to HCDSG that monthly communication via a formal report would be presented at each HCDSG meeting, and would include any issues identified in the previous month, and the progress/position of each Trust. This information would be used by HCDSG to prepare a report to CSB and AGG (via DFCOs and DoCs), so that Finance in particular were aware of the financial pressures/opportunities and could then communicate with Trusts finance departments. According to the plans presented by the working group, all Trusts are expected to have prepared a business plan to return to the May HCDSG meeting. It was agreed that AP would draft a template on behalf of the working group by the end of the week and this would be shared with Trusts. The working group would escalate any concerns to HCDSG. CS agreed to communicate a holding email to Chief Pharmacists later that day and to copy AP in.

	Action: Working group (via AP) to send a template business plan to all Trusts by the end of the week, a holding email would precede this from CS to all Chief Pharmacists. **Action: GMSS to take the points raised from the discussion and action through the working group as necessary, with an assurance report containing sufficient information for HCDSG to manage the strategic aims of this work and report as necessary into CSB and AGG.**
2.2	**Treatment choices in Wet AMD – setting the direction for a GM working group** GMMMG Clinical Standards Board (CSB) at their April meeting requested that a task and finish group be formed to undertake a review of the treatment choices in Wet Age-related Macular Degeneration (wAMD), in order that a GM position may be reached concerning the use of unlicensed bevacizumab as a possible treatment option. This request was directed to HCDSG who agreed to communicate their thoughts to the GMMMG Chairs meeting in the coming week. A summary of the available evidence and National opinions was presented to the group and included the 2015 national letter from Clinical Commissioners to Jeremy Hunt, NICE Guidance NG82; Age-related macular degeneration (published January 2018), a Joint Statement from the Royal College of Ophthalmologists and NHSE Clinical Commissioners in January 2018 and a statement from the GMC in January 2018. Recent communication from Dr Keith Ridge (Chief Pharmaceutical officer) to Chief Pharmacists was also included. The key points from this summary highlighted the NHSE position i.e. that the use of unlicensed bevacizumab for wAMD is not supported, GMC prescribing advice regarding situations where prescribing of unlicensed products may be considered and the MHRA direction of the supply of unlicensed medicines i.e. that “The requirement for a “special need” relates to the special clinical needs of the individual patient. It does not include reasons of cost, convenience or operational needs”. The paper suggested further points that a working group may need to consider i.e. the availability of stability data for Avastin following its repackaging as a special product, the legal responsibilities of Chief Pharmacists and locality pharmacist advisers in issuing a GM position, and the judicial review currently tabled for the NE of England CCGs concerning their proposed use of Avastin for AMD. Funding implications of such a proposal were briefly noted, although it as noted that the figures presented were likely not an accurate reflection of the GM position currently. There was comment from some group members that they felt the paper was one-sided, the authors responded that the paper was simply stating the current information available, and felt a responsibility to highlight the current legal position and responsibilities of this situation to readers.

	Discussion around savings to the health economy versus the legalities surrounding the prescriber and provider responsibilities followed, Chief pharmacists raised serious concern that this proposal was asking them to consider practice that goes against professional advice. There was query as to the capacity of GM ophthalmology departments to treat the additional patients proposed through the savings made by this project, and whether there was an appetite from ophthalmology specialists to consider the use of this product. Comment was made that there was a potential to engage private providers if NHS providers were unable to support this service. The group agreed that this would not be the preferred situation. Members agreed that a working group would need to be well-represented from both Provider and Commissioners arms and that it should be independently led. It was crucial that GM finance and commissioner bodies were well-informed and understood the risks associated with this proposal, and that a comprehensive briefing paper would need to be prepared. It was agreed that HCDSG should maintain its focus on biosimilar implementation particularly given the financial opportunities that could be realised from the adalimumab biosimilar switch, and that HCDSG would not have capacity to oversee a working group to look at treatment choices in wAMD. It was confirmed that CSB had already asked that this working group report directly back to CSB. CS agreed to raise this topic at the GM Chief Pharmacists meeting for discussion and views and would report back to the GMMMG Chairs meeting. **Action:** HCDSG members attending GMMMG Chairs to feed back a summary of this discussion at the GMMMG Chairs meeting.
2.3	**National Pharmaceutical Supply Group Position Statement (December 2017): Signing of Non-Disclosure Agreements by Hospital Trust Chief Pharmacists** *This item was deferred to the May meeting*
2.4	**Blueteq use across GM** *This item was deferred to the May meeting*
3. Horizon scanning and work planning	
3.1	**RDTC MHSD (includes MHRA DSU links) (Apr 2018) and work plan** *This item was deferred to the May meeting*
4. Communication from other groups	

	• Medicines Optimisation Clinical Reference Group • HIM • Chief Pharmacists • RMOC Updates from RMOC, MOCRG, HIM and GM Chief Pharmacists had been included in the discussions above concerning adalimumab biosimilar. It was also noted that HIM were looking at local implementation of the COPD pathways, Sepsis and the Care of the deteriorating patient. GM Chief Pharmacists were due to meet on the 26th April.

5. AOB

	Nil

Date of next meeting: Wednesday 23rd May 2018 – Swinton room, Mezzanine Floor, St James's House

Attendee	F	M	A	M	J	J	A	S	O	N	J
Charlotte Skitterall Chief Pharmacist UHSM		✓	✓								
Rachael Fallon (or Danielle Timoney or Vanessa Reid) Deputy Director of Pharmacy & Head of MO CMFT		A	✓								
Steve Simpson Chief Pharmacist Bolton Trust		✓	✓								
Paul Buckley Chief Pharmacist Stockport Trust		A	A								
Darren Staniforth HCD Pharmacist UHSM		A	✓								
Selwa Elrouby or Andrea Marrosu HCD pharmacist or MI pharmacist SRFT		✓ SE	✓A M								
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								
David Dolman Deputy Chief Finance Officer Stockport CCGs		A	A								
Glenn Harley NW Procurement lead NW		✓	A								
Connie Chen GP Manchester CCG		A	✓								
Consultant rheumatologist (Therese Brammah, Sahena Haque, Louise Mercer, Surabhi Wig (Bolton)or Charlie Filer)		✓ SH	✓ SW								
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								
Monica Mason Principal pharmacist RDTC		✓	✓								