**Chair:** Charlotte Skitterall, Chief Pharmacist, UHSM
**Vice Chair:** Claire Vaughan, Head of Medicines Optimisation, Salford CCG
**Enquiries:** Monica Mason, Head of Prescribing Support, RDTC
(tel : 0191 213 7855, email: rdtc.rxsupp@nuth.nhs.uk )

# HIGH COST DRUGS SUBGROUP

**Wednesday 28th March 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)<br>Apologies as per register were noted. |
| 1.2 | **Conflicts of Interest**<br>Nil |
| 1.3 | **1. Minutes**<br>The minutes were agreed as accurate.<br>**Action: MM to upload to the GMMMG website** |
| **1.4** | **Actions and Matters arising**<br>*BSR Biologics register for RA.*<br>The group were updated on recent discussions with the holders of the biologics register. Not all biosimilars are supporting the register, however assurances had been given that the choice of biosimilar within GM Trusts was not influenced by whether or not the product was supporting the register. Post marketing surveillance of biosimilar products is undertaken by terms of the licensing process rather than information gathered by this register, and there was no stipulation that every biosimilar product needed to be listed on the register. There was some query from the group as to the role of the register and the consequences of the usefulness of information gathered if it did not reflect all biologic products in use across GM. It was suggested that the registry holders be invited to a future HCDSG meeting for further discussion.<br>The issue of adalimumab biosimilars and their inclusion on the register should be included as part of the adalimumab biosimilar implementation plan for GM.<br><br>**Action:** MM to invite registry holders to a future HCDSG meeting to discuss the remit of the RA register. Members of the adalimumab biosimilar implementation working group to investigate the inclusion of adalimumab biosimilars on the register. |

| | |
|---|---|
| | *GM wide optimum management of biologics:*<br>The group noted recent discussions from the GM rheumatology group meetings (attended by HIM and HCDSG reps) and agreed that that it would not be possible for multiple topics i.e. wastage, dose tapering and biosimilar switch programmes to be tackled in one work stream. It was suggested that HCDSG prepare individual biologics optimisation plans to this group through these meetings, where it would be proposed that HIM work to implement these plans across GM. This work would be tabled at a later stage, to enable the adalimumab biosimilar plan to take priority.<br>**Action:** HCDSG to table individual biologic project plans for development.<br><br>*Dupilumab for atopic dermatitis: review of evidence*<br>The group approved the revised recommendation to include the stricter criteria proposed. It was understood that Dupilumab is a specified high cost drug and CCGs will be the responsible commissioners for dupilumab for this indication. The annual cost per patient is around £16,450, if it is assumed that 50% of the patients with severe AD are treated at a cost of £16,450 per year this would represent an estimated cost pressure of £49,300 per 100,000 population (£1.38 million annually across GM based on a 2.8 million population). The group noted feedback from GM specialists who had reported that about 30 to 50 patients had been identified as candidates for dupliumab but that further patients may be identified and that this number may rise to 150 patients across GM. IF 150 patients were to receive duplimumab for a year this would cost the GM health economy about £2.55 million. HCDSG asked that this financial implication be communicated to CSB.<br>Query was raised as to whether the commissioners had planned for this impact, it was noted that some Trusts and commissioners had accounted for this agent within planning rounds, but those present were unable to respond for all GM organisations. The possibility of more robust GM wide horizon scanning and financial planning had been discussed at a previous meeting and was scheduled to be undertaken by HCDSG in the early summer. Query as to the progress of the approval of the GM PBRE spreadsheet was raised, it was confirmed that it has been submitted to AGG (via GM Finance and Commissioning) and is awaiting approval.<br>*Post meeting note: Following its first Committee meeting NICE published an appraisal consultation document "not recommending" dupilumab, as the cost effectiveness estimates range from £30k to £78k per QALY. We now expect any positive approval from NICE to be dependent on a patient access scheme to ensure cost effective access to this treatment. HCDSG will continue to liaise with GM dermatologists to further define a place in therapy for this agent, should this information be required to support implementation of a positive NICE TA which is currently expected in August 2018.*<br>**Action:** MM to redraft statement to include the proposed tighter criteria for treatment and highlight financial implications to CSB.<br><br>*GMMMG Biologics Pathway for psoriasis: 3rd and 4th line treatment*<br>Discussions with dermatology specialists confirmed that third and fourth line treatments will remain within the tertiary centre, Salford FT.<br>**Action:** Manchester CCG to communicate this to CMFT |

| | |
|---|---|
| | *Blueteq: application to highlight compliance with NICE TAs*<br>A paper detailing the reporting function of Blueteq is in development, further work is required to address discussions on assurance reporting at a GM level.<br>**Action:** Authors of paper to continue discussions to determine appetite for Blueteq or an alternative system to provide NICE TA assurance at a GM level<br><br>*Gain Share assurance paper for biologics*<br>The biosimilar adalimumab assurance report was discussed under the adalimumab biosimilar implementation plan discussions. However it was noted that Directors of Commissioning have also requested a GM level High Cost Drugs assurance paper. The BI tool dashboard provides some reporting of biosimilar uptake patterns, but it is recognised that inconsistencies with data submission from some Trusts persist. In addition the GMSS Challenge Reports communicate HCD outliers to Trusts, and seeks reimbursements where appropriate, however HCD reporting is not completely available from the BI tool. The group suggested that it is the responsibility of lead commissioners to provide assurances to the HCDSG around HCD spend, and that the HCDSG will then issue assurance to CSB and AGG. Any identified issues that affect GM performance will be highlighted through this route. GMSS to draft reporting template.<br>**Action:** GMSS to draft a reporting template to be used by lead commissioners to communicate assurance on HCD performance to HCDSG, who will report in turn to CSB and AGG. |
| **2. Medicines Optimisation** | |
| **2.1** | **Adalimumab implementation plan**<br>Members of the GM adalimumab biosimilar implementation working group presented a paper setting out the planned implementation of biosimilar adalimumab across GM. The plan aims to ensure rapid uptake of the best value product and realisation of maximum savings to the NHS across GM, it was also agreed that the introduction of biosimilar adalimumab should follow a standard GM project management approach. This would reduce workload and avoid duplication of effort in individual trusts; improve standardisation, reduce variation in uptake and ensure consistency for the patients of Greater Manchester. In GM, the spend on CCG commissioned adalimumab for financial year 2016/17 was just over £16.2m, which accounted for nearly 20% of the total high cost drugs bill. In 2017/18 the data for first 10 months shows nearly £14.3m spent on adalimumab, with over £17m predicted for the total yearly expense. However the working group stressed to the HCDSG that the potential saving is difficult to predict accurately until the price of the biosimilar medicines is known. An update was provided from the NW procurement lead on the tendering and procurement process and the progress to date. It was noted that there are many additional layers to the calculation of savings that add to the complexity (e.g. existing homecare arrangements, number of biosimilars introduced.) The working group explained that they have met with all GM Trusts, have liaised with regional and national bodies including the RMOC to gather the most recent and relevant information available.<br>HCDSG asked that an operational plan for Trusts to deliver the switch to a biosimilar product be included within the scoping paper from the working group. It was clarified by the working group that the detailed implementation plan by Trust would follow later |

| | |
|---|---|
| | in the process, and that the working group are preparing a GM level plan, but that it would be the responsibility of individual Trusts to develop their own operational plans at specialty level.<br>The membership of the working group was discussed, it was requested that more clinical staff were invited onto this group, in particular rheumatology nurse specialists in order to ensure that there was good clinician engagement from the start.<br><br>HCDSG agreed that the plan presented was thorough but required more urgency, stating that the working group should meet monthly, but with continuous individual Trust meetings in between. Further clarity was required as to the individuals responsible for each part of the plan, and that communication expertise was essential to the success of this plan. Risk registers were requested, detailing both strategic and operational risks, with further clarity on the measures proposed, and the reporting arrangements. The plan needs to confirm whether "new patients" or existing patients only are included.<br><br>The working group is being facilitated through GMSS who confirmed that they had provided the necessary resource to this project to support it to completion. However Commissioners and Trusts would need to ensure they had the resource to implement the plan, and scoping of current resource levels and source had been requested. It was recognised that the success of this plan was dependent on support from the GM Trusts, but that it was the responsibility of commissioners to engage with their Trusts to ensure implementation of this plan in adequate time for its benefits to be realised. Contracts should be updated accordingly. Commissioners are asked to liaise with their Trusts to ask that engagement with Abbvie does not affect GM biosimilar uptake, and to encourage engagement with the GM biosimilar implementation plan. It was noted by the group that the start date for the introduction of adalimumab biosimilar introduction is unknown at this time.<br><br>**Action:** Working group to action the points raised above within their current plans and to provide a monthly assurance report to HCDSG. A summary of the plan to date to be submitted to CSB. |
| **2.2** | **Commissioning framework for biological medicines: "best value" clarification**<br><br>A paper was presented to provide an update on the implementation of the NHS England and NHS Improvement document "Commissioning framework for biologic medicines", and to define the criteria to be used when identifying the "best value" biologic, as this had not be defined by NHSE. It was noted that the group had approached RMOC for this definition but that no definition was available, nor was any other local or national criteria found to be available.<br><br>The group considered the criteria presented, and queried whether they should be weighted. It was agreed that it would be most appropriate to weight the criteria within a product rather than for all products. It was also agreed that the criteria should consider if a product was included in a regional tender. This paper was approved for submission to CSB, who would also be asked whether they wished these criteria to be shared with others out with GM, in the absence of any national guidance. |

| | |
|---|---|
| | **Action:** MM to submit paper to CSB |

## 3. Data

| | |
|---|---|
| **3.1** | **Biosimilar data dashboard – monitoring and assurance**<br><br>The group noted that data quality is a continuing issue, although in a much better position than a year ago. The release of biosimilar reports appears to be helping drive the need for improved data quality. GMSS continue to work with stakeholders to rectify outstanding data submission issues. |

## 4. Horizon scanning and work plan

| | |
|---|---|
| **4.1** | **RDTC MHSD and work plan**<br><br>The February and March horizon scanning documents were considered and the work plan will be updated accordingly. It was confirmed that erenumab and galcanezumab for migraine were being tracked by the RDTC and information would be provided to the HCDSG following EMA positive opinion.<br><br>The work plan format would be refreshed prior to the May meeting as agreed. |

## 5. Communication from other groups

| | |
|---|---|
| | Updates from RMOC, MOCRG, HIM and GM Chief Pharmacists had been included in the discussions above concerning adalimumab biosimilar. No other updates were discussed. |

**Date of next meeting:** Wednesday 25th April 2018, 10am until 12 noon in Community Room 1, Pendleton Gateway, Salford.

| Attendee | ~~F~~ | M | A | M | J | J | A | S | O | N | J |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Charlotte Skitterall<br>Chief Pharmacist<br>UHSM | | ✓ | | | | | | | | | |
| Rachael Fallon (or Danielle Timoney or Vanessa Reid)<br>Deputy Director of Pharmacy & Head of MO<br>CMFT | | A | | | | | | | | | |
| Steve Simpson<br>Chief Pharmacist<br>Bolton Trust | | ✓ | | | | | | | | | |
| Paul Buckley<br>Chief Pharmacist<br>Stockport Trust | | A | | | | | | | | | |
| Darren Staniforth<br>HCD Pharmacist<br>UHSM | | A | | | | | | | | | |
| Lindsay Harper (or Selwa Elrouby)<br>Director for Pharmacy<br>SRFT | | ✓ SE | | | | | | | | | |
| Robert Elsey<br>Specialist Pharmacist<br>PAT | | ✓ | | | | | | | | | |
| Claire Vaughan<br>Head of MO<br>Salford CCG | | ✓ | | | | | | | | | |
| Jeanette Tilstone<br>Head of MO<br>Bury CCG | | A | | | | | | | | | |
| Susan McKernan<br>Senior MO Adviser<br>North Manchester CCG | | A<br>✓ KL | | | | | | | | | |
| Jole Hannan<br>CCG Interface Pharmacist<br>Bolton CCG | | A | | | | | | | | | |
| David Dolman<br>Deputy Chief Finance Officer<br>Stockport CCGs | | A | | | | | | | | | |
| Glenn Harley<br>NW Procurement lead<br>NW | | ✓ | | | | | | | | | |
| Connie Chen<br>GP<br>Manchester CCG | | A | | | | | | | | | |
| Consultant rheumatologist<br>(Therese Brammah, Sahena Haque, Louise Mercer or Charlie Filer) | | ✓ SH | | | | | | | | | |
| Sarah Jacobs<br>Strategic medicines optimisation pharmacist<br>GM Shared Service | | ✓ | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Andrew Martin<br>Strategic Medicines Optimisation Pharmacist<br>GM Shared Service | | ✓ | | | | | | | | | |
| Anna Pracz<br>Medicines optimisation pharmacist<br>GM Shared Service | | ✓ | | | | | | | | | |
| Brian Galea<br>Systems Administrator<br>GM Shared Service | | A | | | | | | | | | |
| Monica Mason<br>Principal pharmacist<br>RDTC | | ✓ | | | | | | | | | |