**Chair:** Susan McKernan, MHCC
**Vice Chair:** Paul Buckley, Stockport FT
**Enquiries:** Daniel Newsome, Principal Pharmacist, RDTC
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# HIGH COST DRUGS SUBGROUP

**Wednesday 27th November 2019, 10a.m. – 12 noon, St James's House, Pendleton Way, Salford. M6 5FW**

## Minutes

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| **1. General Business** | |
| 1.1 | Welcome and apologies (See register in appendix 1). |
| 1.2 | **Declarations of interest**<br>None declared |
| 1.3 | **Minutes from the previous meeting**<br>October minutes were approved<br>**Action:** DN to publish minutes to GMMMG website |
| **1.4** | **Actions and matters arising**<br>See updated action log |
| **Governance** | |
| **2** | **Workplan**<br>The group received the updated HCD workplan. An update was provided from the HCDStG where the pathways work was discussed as this now needs to be considered alongside the GM work being led by the elective reform programme board. Priority work streams will be dermatology, ophthalmology and gastroenterology. The programme director is Laura Marsh with whom the HCDStG are liaising and a call is being set up by the chair of this group to discuss how GMMMG can support the boards priority workstreams.<br>An update was received from the HCDStG to include the adalimumab lessons learned paper, which will be shared with HCDOG before the end of November, when finalised.<br>HCDStG agreed with the recommendations on the dupilumab assurance report and want this to be made more visible to national and local organisations as an example of the benefit of commissioning for outcomes.<br>**Action**: RDTC to work with JCT to draft case study report of dupilumab assurance |

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| | work for onward dissemination |
| **Managed entry of HCDs** | |
| **3** | **NICE/MHRA/horizon scanning**<br>The relevant updates were discussed.<br>A NICE TA for Xeomin (TA605) has been published recommending this product for the treatment of chronic sialorrhoea in adults. AMarr pointed out that the administration method is different from the other available products currently used for this indication which despite being “off-label”, Botox is the preferred product and botulinum toxin brands are not interchangeable. The GM neuroscience network is not prepared to advocate use of this product due to the need for a change in practice and the associated clinical risk of doing so. The HCDOG agreed that the product should be made available via the formulary for use in GM, in order to fulfil commissioners responsibilities under NICE even if clinicians declined to use it. The GM botulinum toxin guidance will require a small revision and the formulary should be amended to ensure the drug is added by brand name.<br>Fremanezumab for migraine has received a negative ACD from NICE and as yet the appeal against the erenumab FAD has not concluded.<br>Esketamine was discussed because initially SPS stated that this would be a PbR-excluded drug despite mental health trusts not having the mechanism to recharge commissioners. Further information now suggests it will be in-tariff but may still have a large impact on GM health economy. The RDTC will ensure that the most appropriate GMMMG subgroup considers the managed entry of this product when NICE publish the TA, expected 18.03.20.<br>The cannabidiol entry was correctly pointed out to be out of date. The FAD for this TA now recommends the use for Dravet and Lennox-Gastaut syndromes with restrictions. It is also anticipated that this drug will be NHSE-commissioned rather than CCG as stated in the document.<br>The implications of Sativex now receiving a positive opinion from NICE as part of NG144 was discussed. Because this is not a tariff-excluded drug it is not within the terms of reference of this group and should be considered by FMESG who are already aware of the guidance and plan to discuss at their upcoming meetings.<br>**Action:** AP to update GM botulinum toxin guidance to reflect TA605 |
| **4** | **GM EUR changes to policy report**<br>The group received a report dated August 2019 which details some changes to the IFR process particularly with regards to the definition of exceptionality.<br>A discussion took place about some of the operational problems encountered when submitting and tracking the progress of IFRs, which include locating the correct paperwork which is not suitable for drug applications and the lack of feedback on requests and decisions taken.<br>Because the GMMMG HCD pathways currently recommend an IFR submission once |

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| | patients have reached the end of the commissioned pathway, there may be a need to have a separate process to consider these.<br><br>AP again pointed out that the GM EUR service review has been approved this then led to recognition that there may be an opportunity for the HCDOG to develop a process to better suit decision making on PbRe drugs, and the comments above could be incorporated. There is a need to align the decision-making by GMMMG HCDs groups with the EUR team and to update current GMMMG IFR process guidance.<br><br>**Action**: JCT to facilitate discussions with EUR team regarding aligning HCD decision making with IFR processes and the updating of current GMMMG documentation. |
| **Managed Entry of HCDs** | |
| **5** | **Sodium oxybate RMOC positioning statement**<br><br>A recent document produced by the RMOC committees has recommended a coherent national commissioning position on sodium oxybate for adults for the treatment of narcolepsy with cataplexy. It noted that GM is already partially aligned to the RMOC position by having an agreement in place to fund the drug for adults transferring from paediatric services.<br><br>Information from SRH clinicians states there are 15 current patients and suggests that up to 6 *new* adults per year could be initiated with the drug were it approved for use. These figures are likely understated as clinicians acknowledge existing arrangements. It is understood that sodium oxybate would be considered for treatment of narcolepsy with cataplexy where other options have been unsuccessful. Solriamfetol is likely to be launched in 2020 for a similar indication however the specialists intend to use these for different groups of patients.<br><br>7 IFRs have been submitted since Feb 18, all but one have been approved.<br><br>A GMMMG review of the drug in July 2017 did not recommend the use in new adult patients, so the group wish to understand if the evidence base has changed since then. If not then it would seem reasonable to maintain the current commissioning position but good rationale will be needed if GMMMG is to reject RMOC recommendations.<br><br>When considering the new products included in horizon scanning, it was agreed that a GM sleep pathway may be required, however this is likely to be a low priority due to the amount of other pathway reviews currently underway and the focus on ophthalmology work.<br><br>**Action:** RDTC to review RMOC statement evidence base and determine if this has changed since the GM statement was published in 2017. |
| **6** | **Liothyronine injection commissioning statement – post consultation**<br><br>Approved with the clarification that the statement also covers paediatric patients<br><br>**Action:** DN to amend statement and submit for GMMMG approval |
| **7** | **Escalated dosing of ustekinumab for Crohn's disease commissioning statement- post consultation** |

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| | The group discussed the consultation comments and acknowledged that although clinicians may be able to loosely define a cohort of patients who may benefit from the proposed treatment, the evidence remains insufficient to routinely commission this at doses outside the licensed frequency. The availability of IFR outcomes from those already approved may moderately support the evidence but is likely to still fall short of the threshold required by commissioners.<br><br>It was noted that an alternative intervention to attempt optimisation of ustekinumab therapy is under clinicians' consideration. This is a single 'recovery' dose of IV ustekinumab administered as the patient experiences loss of symptom control in order to allegedly boost response. Again, evidence is believed to be very limited to support this unlicensed use of ustekinumab. Manufacturers appear to allow such use of ustekinumab under a scheme where the 'recovery' dose would cost £1. It was decided that this could not be supported by commissioners because it was off-label usage of the drug and therefore the price could not be guaranteed.<br><br>The HCDOG approved the statement with minor amendments to the wording.<br><br>**Action:** DN to amend statement and submit for GMMMG approval |
| **8** | **GM statement on PCSK9 inhibitors for the treatment of hypercholesterolaemia**<br><br>The group were asked to review a statement created in 2017 which is now due for review. It was felt that a target reduction in LDL-C was still relevant and useful despite it not being reflected by the NICE TAs. This was because the NICE cost-effectiveness analysis done at the time suggested the treatments had a cost per QALY close the threshold at which NICE would not normally approve, therefore some assurance was required that benefit was being obtained. A 30% reduction in LDL-C was agreed by HCDOG to be a reasonable gauge of effectiveness. A technical update was approved with the amendment of the wording "lipidologist" to "lipid specialist" after which the document can be published to GMMMG website.<br><br>Due to variation in prescribing and the availability of Blueteq data, the group recommended the collation of a report on outcomes which should be considered by HCDOG when ready.<br><br>**Action**: DN to amend document as agreed and publish to website.<br><br>**Action**: JCT to produce a Blueteq report on the PCSK9 inhibitors showing outcomes. |
| **Monitoring and assurance** | |
| **9** | **GM biosimilar uptake assurance report – October 2019**<br><br>AP presented the most recent data for biosimilar uptake across the GM providers; overall the adalimumab biosimilar uptake was at 74% at the time of report writing – mid October. Variation in uptake continues between and within trusts. Stockport FT gastroenterology and WWLFT's dermatology have not yet reported switching. Bolton are due to begin switching in Q4 2019-20.<br><br>Some discussion was had on the rate of "switchbacks" to originator currently observed with etanercept but that it was too early to tell the rate at which this is happening with adalimumab (if at all). AL commented that this had been discussed regionally in the case of etanercept and is unlikely to be due to switchbacks but that a stable cohort of |

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| | patients have continued with Enbrel whilst the numbers of patients getting biosimilar has declined (due to preferential use of biosimilar adalimumab), which when combined with the expected loss of efficacy experienced by etanercept treated patients makes it appear that a % shift to originator has occurred. However prices of biosimilar and originator are so similar that the financial implications and impact of switchbacks are minimal, and that the focus is on adalimumab at present.<br><br>CV noted that Pennine Acute trust will be applying adalimumab reference price from Jan 2020.<br><br>**Action:** HCDOG to continue to monitor |
| **10** | **Optimisation of Blueteq across GM**<br><br>Item not discussed due to time constraints and has been deferred to the Jan meeting. |
| **11** | **EMA advice regarding tofacitinib prescribing for patients at risk of blood clots**<br><br>The EMA published this advice on 31st October 2019; its relevance to the HCDOG is that there is likely to be a number of patients for whom in light of the new evidence on safety this drug is no longer appropriate. They may require a switch to another drug which under current pathway guidance would utilise one of the permitted treatment steps. HCDOG agreed that where a safety recommendation is published by an appropriate regulatory body affected patients may switch to a more suitable drug without utilising a pathway treatment step. This should be written into the pathways as they are updated.<br><br>It would be useful to have numbers affected to quantify the GM impact.<br><br>**Action:** Numbers of affected patients to be fed back to HCDOG by trusts.<br><br>**Action**: DN to draft a proposal for HCDStG approval. |
| **Communication from Subgroups and Associated Committees** | |
| **12** | Updates were received as available from the GM HCD optimisation network, MO CRG, HiM, GM Chief Pharmacists and MO leads and RMOC. |
| **AOB** | |
| **13** | AMart reminded the group the judicial review on the Avastin case was heard last week and a decision is expected before Christmas.<br><br>The manufacturer of Collagenase (Xiapex) has chosen to cease production by the end of December 2019. It is the only collagenase product licensed to treat Dupuytren's contracture and it is not yet known if a replacement product will be made available. |
| **Date of next meeting: 22nd January 2020, 10-12 noon at St James House, Salford (Swinton room). NOTE DECEMBER MEETING IS CANCELLED.** | |

**Appendix 1 – attendance register**

| Attendee | J | A | S | O | N | D | J | F | M | A |
|---|---|---|---|---|---|---|---|---|---|---|
| Steve Simpson<br>Chief Pharmacist, Bolton Trust | ✓ | ✓ | A | A | ✓ | | | | | |
| Paul Buckley<br>Chief Pharmacist, Stockport Trust | ✓ | A | ✓ | ✓ | ✓ | | | | | |
| Darren Staniforth<br>HCD Pharmacist, MFT | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | |
| Andrea Marrosu<br>HCD pharmacist, SRFT | A | ✓ | A | ✓ | ✓ | | | | | |
| Chris Astbury<br>HCD Pharmacist, Pennine Acute Trust | ✓ | A | ✓ | A | ✓ | | | | | |
| Jacqueline Coleman<br>Specialist Interface Pharmacist, Stockport CCG | | | ✓ | ✓ | A | | | | | |
| Susan McKernan (Chair)<br>Senior MO Adviser, MHCC | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | |
| Jole Hannan<br>CCG Interface Pharmacist, Bolton CCG | ✓ | A | ✓ | A | A | | | | | |
| Consultant rheumatologist<br>(Therese Brammah, Sahena Haque, Louise Mercer, Surabhi Wig, Audrey Lowe or Charlie Filer) | ✓ LM | ✓ AL | ✓ SH | ✓ SH | ✓ AL | | | | | |
| Claire Vaughan<br>Head of MO, Salford CCG | | | | | ✓ | | | | | |
| Andrew Martin<br>Strategic MO Pharmacist, GM JCT | ✓ | ✓ | ✓ | A | ✓ | | | | | |
| Anna Pracz<br>Senior MO pharmacist, GM JCT | A | ✓ | ✓ | ✓ | ✓ | | | | | |
| Monica Mason<br>Head of Prescribing Support, RDTC | ✓ | ✓ | | | | | | | | |
| Carol Dolderson<br>Lead Pharmacist, RDTC | | ✓ | | | | | | | | |
| Dan Newsome<br>Principal Pharmacist RDTC | | ✓ | ✓ | ✓ | ✓ | | | | | |