Chair: Susan McKernan, MHCC
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HIGH COST DRUGS SUBGROUP

Wednesday 23rd October 2019, 10a.m. – 12 noon, St James's House, Pendleton Way, Salford. M6 5FW

Minutes

1. General Business	
1.1	Welcome and apologies (See register in appendix 1). The group welcomed Glenn Harley, who had been invited to attend.
1.2	**Declaration of Interest** None declared
1.3	**Minutes from the previous meeting** September minutes approved pending the clarification within the section on ustekinumab that there is no current mechanism to obtain outcome data for approved IFR requests. The group then discussed the process by which outcome data could be obtained from approved IFRs, some data can be provided but this is on an individual patient basis in response to a single CCG's request. In order to replicate for all CCGs there are IG issues that need to be explored. **Action:** DN to amend minutes as above and publish to GMMMG website
1.4	**Actions and Matters arising** There was a strong consensus within the group that the adalimumab biosimilars lessons learned report should be shared with the HCDOG as well as with a wider audience, particularly finance teams. HCDStG currently have the report and need to approve for submission to CSB, at which point it can be shared.
Governance	
2	**Workplan** The group received the updated workplan. It was pointed out that the document is not clear on which items have been completed and those which have slipped. The current situation with erenumab was discussed; the data shows there are currently

	about 40 patients receiving the drug on the FOC scheme. Analysis of this indicates that it is effective in only around 50% of those treated, but that it provides benefit from the 2nd injection and can reduce symptoms by 80-90%. The treating clinicians have concluded that the 140mg dose is significantly more efficacious than the 70mg strength, resulting in the most recently treated patients receiving this dose initially. There were no severe ADRs reported, injection site reactions and GI symptoms have been the only side effects noted. The manufacturers assured there will be no cost to commissioners for 3 years from this cohort unless NICE amends their position of not recommended Once SRFT have discussed at their D&T this issue will return to HCDOG for discussion. **Action:** DN to update workplan to reflect current progress.
Managed entry of HCDs	
3	**NICE/MHRA/Horizon scanning** The relevant updates were discussed. Bezlotoxumab TA601 has been terminated due to no evidence being submitted by the manufacturer, it was noted a GM-wide commissioning statement is in the process of being approved but that this did not recommend the use of the drug and so did not require amendment. An infliximab biosimilar (Remsima) is being made available as a subcutaneous formulation to treat RA at some point in 2020. If this is to be used the cost impact, including savings through the use of homecare and the pressure this will put on providers, needs to be understood. The option will be flagged to the RA working group for inclusion in the revised pathway but numbers are expected to be small and the impact low so it was felt a commissioning statement was not required at this point. The greatest use of infliximab IV is currently for IBD indications, so the use of the s/c product would be off-label, notwithstanding it would be useful to understand the interest for use from gastroenterology. This would not be automatically commissioned and would require a position statement if approved for use. **Action:** JCT to amend BI tool to capture both formulations of Remsima **Action:** AMarr and DS to discuss with gastroenterology and gauge interest for off-label use.
4	**Horizon scanning – Prescribing Outlook** The group considered the drugs and indications listed as likely to have the highest GM impact in terms of spend and/or commissioning implications. It was recognised that the absence of the cost-calculator may require some of these items to come back to HCDOG for further discussion and/or action at a later date. • Vedolizumab s/c for IBD may have an impact if it replaces adalimumab biosimilar first line. The thoughts of the group were that this is unlikely because it is not considered as clinically effective as adalimumab and a new formulation would not alter its position in the pathway. • Manufacturers may already be offering a FOC scheme for galcanezumab. For this to be utilised it should be in line with the GM policy on FOC schemes and GMMMG should learn the lessons from the erenumab scheme and ensure

	transparent data collection. • There was some debate whether esketamine is really a PbRe drug. It was stated that MH services are not strictly CCG-commissioned and there is no mechanism to recharge for use of this drug. The concerns regarding the abuse potential were also noted. It is expected to have a status of controlled drug. • Solriamfetol could have a large cost implication and should be included in the proposed GM sleep service pathway, and should therefore be flagged to this working group and PaGDG. • There could be a large demand for roxadustat (oral) as an alternative to injectable EPO. The group were aware of cohorts of patients for whom this would be appropriate e.g. where logistics issues exist for those unable to self-inject in primary care. The financial impact is clearly price dependent and because NICE are not planning to appraise the drug, the entry may need to be managed, however the group agreed to wait for pricing information before deciding how to proceed **Action:** DN to review proposed mechanism for recharges of esketamine and confirm if this is truly CCG-commissioned.
5	**Biosimilar teriparatide** The HCDOG received and considered the information contained in the teriparatide biosimilars proposal. Due to the work required, the potential difficulties in switching mid-course and the relatively small savings on offer, it was agreed that option b. would be the most appropriate. This means new patients should receive the biosimilar and existing patients are remain on the originator until the end of the fixed 24-months course. This would mean that the uptake levels would be different than non the GM biosimilar commissioning framework (at least 40% for the first year and at least 80% for the second year of availability provided no significant changes to the framework). The group decided a GM statement was not required due to the existing GM policy and framework on adoption of best value biosimilars, and that a letter to providers would be sufficient. This will be communicated to HCDStG along with the recognition from HCDOG that it will not be possible to achieve 80% uptake among existing patients as specified on the framework. **Action:** DN to communicate recommendation to HCDStG
Monitoring and assurance	
6	**Dupilumab – atopic dermatitis assurance report** The group acknowledged the dupilumab assurance report and noted the current number of patients is similar to that which was predicted; 143 actual vs 150 predicted. Outcomes are available for 20 patients and all were positive in terms of meeting NICE criteria (decrease in both EASI and DLQI scores). The group were informed that the pathway is now likely to be saturated and very few new patients are expected due to dermatology capacity issues at SRFT. It was agreed that the report provides assurance that the drug is being used appropriately and that outcomes are good. It

	was suggested that as it is a good example of commissioning for outcomes the work could be shared with other decision making groups. **Action:** Communicate to HCDStG, continue to monitor at 6-monthly intervals.
7	**IFR report** A report showing the trends and themes of drug IFR between March and September 2019 was presented to HCDOG. This included 70 cases, of which ustekinumab and tofacitinib were the most frequently requested drugs and no new trends were identified. The group felt that the absence of trends shows that the issues are being addressed through the production of pathways and commissioning statements. AP has scheduled some training with the EUR team to improve the processing of drug IFRs, however the group thought that some information on the review of EUR processes would be helpful after it was mentioned that the GM exceptionality definition has changed. Continue to monitor on 6 monthly basis. **Action:** DN to consider if the IFR document on GMMMG website requires a review and feedback to group on EUR review.
8	**GM biosimilar uptake assurance report – updated September 2019** An update of the biosimilars assurance report was received by HCDOG. Overall adalimumab biosimilar uptake is now at 70%. Bolton FT has not yet switched any patients and this represents around 20% of the total Humira prescribing in GM. The group considered if HCDOG could support the trust to begin a switching programme but are led to understand the delay is due to internal finance issues and is being escalated by HCDStG and concluded that no action is currently required. The decrease in biosimilar etanercept usage noted by HCDOG in September has been discussed with GM providers, and assurance given to the group that this does not represent switch backs to originator rather is due to processing of homecare prescriptions and overall reduced patient numbers. The uptake of biosimilar adalimumab remains a priority. JCT will continue to monitor and escalate as appropriate. **Action:** Share lessons learned review document when available.
9	**PbR tariff-excluded high cost drugs list – October 2019** The annual HCD list spreadsheet was shared with the group for approval on updates made to it in October 2019. The spreadsheet is used by some MO teams to communicate any changes with commissioning teams and has been requested quarterly. It was recognised that there are different processes happening in GM around this and that a single process should be implemented. The comments received from HCDOG recommended incorporating version control into the document title and a column to denote the date on which a decision was taken, along with some formatting changes which will be communicated to the author. The group recognised that updates will only be made once a decision has already been ratified by CSB so agreed that any changes to the list in year need only be approved by HCDOG as a sense check before circulating to commissioning teams. **Action:** AP and DN to work with AMart to respond to the comments made, and

	circulate by email to HCDOG for approval.
Communication from Subgroups and Associated Committees	
10	Updates were received as available from the GM HCD optimisation network, MO CRG, HiM, GM Chief Pharmacists and MO leads and RMOC.
AOB	
11	Awareness of an industry-sponsored event discussing HCDs pathways in psoriasis organised by Pharmacy Management was raised. The response from HCDOG was that this event has now been cancelled. GH informed the group of some work that the procurement team are undertaking with UKMI to track the entry to market of generic medicines following patent expiries, of interest to HCDOG would be details of products such as generic sodium oxybate. The intention is to group new generic products together and include in the next round of procurement. A document is being prepared and will be shared when finalised.
Date of next meeting: 27th November 2019, 10-12 noon at St James House, Salford (Broughton Suite). NOTE DECEMBER MEETING IS CANCELLED.	

Appendix 1 – attendance register

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