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 26th February 2020, 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). Despite the absence of a chair the meeting was quorate according to the terms of reference. However it was agreed in the absence of a formal chair that the minutes and actions should be shared amongst all members for ratification.
1.2	**Declarations of interest** AP declared she has been selected to be a member of the NICE technology appraisal committee B.
1.3	**Minutes from the previous meeting** No minutes were taken from the telephone meeting on 22.01.20 **Action:** No further action
1.4	**Actions and matters arising** See updated action log
Governance	
2	**Workplan** The group received the current HCD workplan.
Managed entry of HCDs	
3	**NICE/MHRA/horizon scanning** The relevant updates were discussed. A new section has been added to this document which asks HCDOG to ratify a number of recommended actions which for this month included an update made in

	January 2020 to the RMOC FOC medicines scheme policy, and some standard wording to be used for new drugs or indications which are due to be considered by NICE for which there is little clinician appetite for use in the interim. The group agreed the following wording to be used in the GM tariff-excluded drugs list document: *"In the absence of a submission from local clinicians this treatment is not routinely commissioned. The publication of a NICE TA will supersede this interim position"* **Action:** DN to take FOC scheme policy forward. AMart to utilise new wording within the GM tariff-excluded drugs list
4	**HCDOG Terms of reference review** It was acknowledged that this item was discussed in the absence of any representative from HCDStG and the nominated chair of HCDOG, therefore the issued could not be fully explored. There was some strong opinion that the GM HCDs governance process should have just the one sub-group, but it was suggested that the value of the operational group could be maximised with some direction from the strategic group and the StG meeting format of bi-monthly was seen as a potential barrier to effective communication. It was pointed out that all work produced by the operational group had been approved by StG and that the management of the system currently appears to be bottom up which was felt to be ineffective. There was recognition that some of the issues discussed by HCDOG are of an operational nature and it would not be appropriate for these to take place in the presence of CCG DoCs and finance. HCDOG agreed that further discussion should only take place when the group's chair was present. **Action**: In the absence of a StG representative the group requested that these comments are be fed into the wider GMMMG subgroups ToR review currently taking place.
Managed Entry of HCDs	
5	**Andexanet alfa commissioning statement – post consultation** The members received the commissioning statement and endorsed for onward approval via the GMMMG process. It was noted that a change of wording within the GM tariff-excluded drugs list to idarucizumab (Praxbind), used for the reversal of the anticoagulation effects of dabigatran, is required. This currently states "IFR approval" which is not appropriate for an emergency treatment and this should be changed to "monitored approval". **Action:** DN to progress the approval of commissioning statement via HCDStG. AMart to amend idarucizumab approval status.
Monitoring and assurance	

6	**RMOC advisory statement – sequential use of biologic medicines** The group received the recommendation from RMOC that advises commissioners should not restrict the number of HCD treatments a patient can receive for a condition based on the previous numbers of treatments received. The group agreed that despite the title of the document, the content and recommendations should apply to both biologic and non-biologic HCD treatments. This statement has generated a significant level of discussion both nationally and locally on how systems ensure they are not in breach of the NHS constitution. The recommendation has been promoted within certain specialties as a "game changer" for patient access to HCDs and some clinicians now feel this allows them to prescribe as many sequential treatments as they see fit. It was recognized that this is a moral standpoint and the clinical implications have not been fully considered by RMOC. It also does not reference the NHS constitution's principle about best use of finite resources and a responsibility for NHS organisations to prescribe cost-effectively. The group were initially asked if they think that current GM policy contained within the GMMMG pathways is restricting patient access to HCDs. This was answered in the affirmative thanks to the IFR process being slow and inconsistent panel decisions across GM as a result of the varying standards of clinical input around the process. It was acknowledged that the IFR process is not fit for this purpose and puts pressure on clinicians due to the significant administrative burden placed on them. However the group accepted there was a need for some form of assurance which should be provided to commissioners in terms of value for money from the biologics services. The group also discussed the clinical implications of the statement and that there is clinical risk associated with continued exposure to anti-TNF drugs, but that flexibility within pathways where patients experienced treatment failure is required. Members stated the need to avoid "post-code prescribing" which they felt RMOC are trying to reduce. Whilst the group agreed that unwarranted clinical variation, particularly in outcomes, is not acceptable, they felt the GM HCD pathways did attempt to prevent this in the region and that the RMOC statement did not change the need to rationalise the many treatment options into a standard pathway to reduce this variation. They therefore agreed a balance between the needs of patients and clinicians on the one hand and commissioners on the other, needs to be struck and that this could be achieved by ensuring clinical oversight is provided for patients using sequential biologics. This could be an MDT or similar process which is linked to provider trust D&T committees, providing both peer challenge to justify use over and above the approved pathways and assurance to commissioners that HCD use is likely to be clinically effective. This process should be informed by pathway authors who need to be contacted for their input and any new processes agreed by GMMMG. **In the interim it was agreed that a need to review HCD pathways and processes following the publication of the RMOC pathway be acknowledged and that until a GMMMG decision on its implementation has been reached, the current processes detailed in the GMMMG HCDs pathways should continue to be adhered to.** **Action:** RDTC to write to HCD pathway authors on behalf of GMMMG to ask for their

	recommendations on how the RMOC statement should be followed
7	**RMOC advisory statement – principles for prior approval forms (Blueteq) and optimisation across GM** The HCDOG received the RMOC recommendation regarding the use of prior-approval (Blueteq) forms and recognised current GM processes are not in line with the principles listed within it. It was noted that at present only a fraction of the data being input to Blueteq is being used (e.g. dupilumab and disease scores for psoriatic arthritis). However there was significant scope to monitor outcomes recorded by different providers but that this was not being done. Two members from the Bolton area acknowledged that Blueteq is not in use locally and that other processes are in place to provide assurance to the commissioner that NICE guidance is being adhered to. Provider representatives confirmed that there is a large administrative burden which they feel is not justified when the data is not being utilised to its full potential and would prefer to use a tick-box or drop down box form similar to those in use by NHSE specialised commissioning. The clinicians present challenged the need for recording a value for the disease activity score(s) and their worth to commissioners when the forms are used to ensure the patient fits the NICE TA criteria. HCDOG acknowledged these scores are largely not required and may be difficult to find in patient records. HCDOG agreed to work to simplify Blueteq forms in line with RMOC guidance pending confirmation from commissioners that the disease scores are not required which should be justified. RMOC also recommends having a committee to consider and approve Blueteq monitoring requirements and forms, the HCDOG agreed that this role fits best within this group. **Action:** Confirm HCDStG are happy to end the use of disease score collection via Blueteq forms
Communication from Subgroups and Associated Committees	
8	**Minutes from GM HCD Strategic group meeting 17th Jan 2020** These were received by HCDOG
9	Updates were received as available from the GM HCD optimisation network, MO CRG, HiM, GM Chief Pharmacists and MO leads and RMOC.
AOB	
13	None raised

Date of next meeting: 25th March 2020, 10-12 noon at St James House, Salford

Appendix 1 – attendance register

Attendee	J	A	S	O	N	D	J	F	M	A
Steve Simpson Chief Pharmacist, Bolton Trust	✓	✓	A	A	✓		✓	A		
Paul Buckley Chief Pharmacist, Stockport Trust	✓	A	✓	✓	✓		A	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			✓	✓	A		✓	✓		
Susan McKernan (Chair) Senior MO Adviser, MHCC	✓	✓	✓	✓	✓		✓	A		
Jole Hannan CCG Interface Pharmacist, Bolton CCG	✓	A	✓	A	A		✓	✓		
Consultant rheumatologist (Therese Brammah, Sahena Haque, Louise Mercer, Surabhi Wig, Audrey Lowe or Charlie Filer)	✓ LM	✓ AL	✓ SH	✓ SH	✓ AL			✓ (AL/SW)		
Claire Vaughan Head of MO, Salford CCG					✓		A	A		
Andrew Martin Strategic MO Pharmacist, GM JCT	✓	✓	✓	A	✓		✓	✓		
Anna Pracz Senior MO pharmacist, GM JCT	A	✓	✓	✓	✓		✓	✓		
Monica Mason Head of Prescribing Support, RDTC	✓	✓					✓			
Dan Newsome Principal Pharmacist RDTC		✓	✓	✓	✓		✓	✓		