NHS
Midlands and Lancashire
Commissioning Support Unit

NHS
Pan Mersey
Area Prescribing Committee

Pan Mersey Area Prescribing Committee

14:00 – 16:00 hours
Wednesday 27 November 2019
The Education Centre, Kent Lodge,
Broadgreen Hospital, Thomas Drive, Liverpool, L14 3LB

Minutes

Members in attendance	**Organisation(s)**
Dr Adit Jain (Chair)	Clinical Lead - Prescribing, Knowsley CCG
Dr Anna Hunter (Deputy Chair)	GP Clinical Lead, South Sefton CCG / Southport & Formby CCG
Dr Rob Barnett	LMC Representative, Liverpool
Carolyn Barton	Senior Quality & Safety Pharmacist, Knowsley CCG
Colin Brennan	Deputy Clinical Services Manager/Surgical Division Lead Pharmacist, Liverpool University Hospitals NHS FT (Aintree site)
Neil Chilton	Medicine Management Clinical Services Manager, North West Boroughs Healthcare NHS FT
Dr Catherine Doyle	GP/Prescribing Lead, Warrington CCG
Alison Evans	Lead Medicines Management Pharmacist, Wirral University Teaching Hospital NHS FT
Dr Claire Forde	CCG Governing Body Member / Prescribing Lead, Halton CCG
Nicola Hayes	Principal Pharmacist, Warrington and Halton Hospitals NHS FT
Anne Henshaw	Senior Medicines Commissioning Pharmacist, MLCSU
Emma Jaeger	Medicines Optimisation Pharmacist, Wirral CCG
Jenny Johnston	Senior Pharmacist, South Sefton CCG / Southport & Formby CCG
Barry Lloyd	Medicines Optimisation Pharmacist, West Lancashire CCG
Dr Shankara Nagaraja	Consultant Intensivist/Anaesthetist, Liverpool University Hospitals NHS FT (Aintree site)
James Parker	Lead Pharmacist – Medicines Optimisation, Liverpool University Hospitals NHS FT (Royal site)
Kathryn Phillips	Medication Safety Officer, Bridgewater Community Healthcare NHS FT
Lucy Reid	Head of Medicines Management, Halton CCG
Maxine Robinson	Deputy Chief Pharmacist, Liverpool Heart and Chest Hospital NHS FT
Claire Sawers	Medicines Optimisation Pharmacist, Warrington CCG
Jackie Szynalski	Pharmacist, Mersey Care Liverpool and South Sefton Community Services Division.
Dr Matthew Van Miert	Consultant Anaesthetist, Wirral University Teaching Hospitals NHS FT
John Williams	Chief Pharmacist, Southport and Ormskirk Hospital NHS Trust
Attendees	**Organisation(s)**
Helen Dingle	Senior Prescribing Advisor, MLCSU
Tamsin Moroney	Senior Prescribing Advisor, MLCSU
Graham Reader	Senior Medicines Commissioning Pharmacist, MLCSU
Caroline Wake	Medicines Optimisation Pharmacist, Wirral CCG

APC/19/76	Welcome and apologies	Action
	The Chair welcomed members and accepted apologies from the following: Anna Atkinson, Catrin Barker, Nicola Cartwright, Kieron Donlon, Danny Forrest (Maxine Robinson attending), Catherine Harding, Jenny Lunn (Claire Sawers attending), Susanne Lynch (Jenny Johnston attending), Joanne McEntee, Dr Sid McNulty, Dr Omar Shaikh and Dave Thornton (Colin Brennan attending).	
APC/19/77	**Declarations of Interest and Quoracy Check**	
	A quoracy check confirmed that this meeting was quorate. There were no declarations of interest for items on the agenda.	
APC/19/78	**Minutes of the previous meeting and matters arising**	
	APC/19/78/01 – Minutes from the Previous Meeting The Minutes were agreed to be an accurate record of the previous meeting on 23 October 2019. The Headache Pathway was approved last month (item 19/72/08); however, GR informed members that the incorrect version had been included on that agenda and now further minor changes are being considered. An updated version will be brought to the APC in due course. ***APC/19/78/02 – Matters Arising*** ***Declaration of Interest forms – reminder*** Those members who have not returned their completed Declaration of Interest form were asked if they could do so ASAP.	**All**
APC/19/79	**New Medicines**	
	APC/19/79/01 – Grey statement summary Dupilumab 300mg injection (Dupixent®▼): A grey statement has been produced for the treatment of chronic rhinosinusitis with nasal polyposis. This will be reviewed when the NICE TA is published (date TBC). Buprenorphine prolonged-release injection (Buvidal®): A grey statement has been produced for this treatment for opioid dependence. This will be reviewed by the FGSG if a formal application for use is received and prioritised for in-year review. ***APC/19/79/02 – Fluocinolone for chronic diabetic macular oedema (part-review of TA301) – APC update*** A partial review of NICE TA301 was published on 20 November 2019 as a separate new TA. TA301 recommends fluocinolone intravitreal implant for DMO only when patients have a replacement (pseudophakic) lens, but this review looked purely at use in patients who still retain their natural (phakic) lens. NICE are upholding their original position of only recommending in patients with a replacement lens. Therefore, because it is a negative TA it will not need implementing as it does not change access to treatment for patients. As there is no December APC meeting this could not be turned around within the mandatory 90 days for NICE TAs but, because there is no change to the current situation, the NMSG believe that this would not breach the 90-day implementation and will bring a black statement to January APC. The APC agreed with this approach.	

	APC/19/79/03 – Rivaroxaban for preventing atherothrombotic events in CAD/PAD – NICE TA607, green statement The NICE TA was published on 17 October. TM went through the details and the NICE costings. It was expected that a large proportion of these patients would not be under the ongoing care of secondary care, so it was felt that the RAG rating had to be green similar to use of DOACs in AF. The NICE Resource Impact Template implies that patients would be identified at their routine annual review, as NICE estimates that steady state will be achieved by the end of 2020/21. The NMSG felt that GPs may welcome more prescribing support to identify appropriate patients, so it was taken to the Cardiac Network Pharmacist Forum for discussion, but they did not feel able to support this request. Members felt that the NICE TA recommendation is too broad, and that it needs to be narrowed down to enable GPs to implement this. It was estimated that over 50% of patients with CAD would be eligible for this treatment, which would have considerably higher cost implications than the costs provided in the NICE Resource Impact Template. The Committee felt that a local decision should be made regarding appropriate patient selection to identify which patients with CAD and which patients with PAD are eligible. There is a separate NICE TA relating to clopidogrel treatment for patients with PAD and it is not clear which patients should receive rivaroxaban plus aspirin instead of clopidogrel. Bleeding risk may preclude certain groups of patients from receiving treatment, but concerns were also raised regarding the assessment of bleeding risk. JP confirmed that this TA has been referred back to the NICE Resource Impact Manager to clarify the breadth of patients and concerns raised by other APCs regarding patient selection and cost implications and he agreed to share any update or feedback he receives. It was noted that other APCs have approved this as 'green', but a number have raised similar concerns. It was also acknowledged that pharma may approach surgeries to identify appropriate patients, initiate treatment or switch treatment. The Committee felt that practices should not engage with pharma representatives regarding this and asked whether each CCG across Pan Mersey would consider issuing a statement to support this. Outcome: 1. To be discussed further in the next CCG Leads meeting with a view to CCG Medicines Management teams issuing a formal recommendation that practices do not sign up to pharma representative projects without consulting with the CCG Medicines Management team first. 2. APC Chair/Professional Secretary to write to NICE on behalf of the APC, raising concerns that the cost impact is a gross underestimate and that the TA recommendation is too broad. It is hoped this will add weight to the concerns raised with NICE from other APCs. 3. AH to discuss with other CSU Medicines Management teams, to establish whether any supporting information has been produced that could be shared. 4. CBr to liaise with vascular surgeons to assist in identifying an appropriate patient group for use in PAD.	**CCG Leads** **AH/AJ** **AH** **CBr**

	APC/19/79/04 – Pentosan polysulfate sodium for bladder pain syndrome – NICE TA610, red statement An unlicensed product has been used previously, but a licensed product is available now. AE went through the details. It is recommended when there has been no response to standard oral treatments and should not be used in combination with bladder instillations. Prescribing must be retained by the specialist as the PAS discount is only available to secondary/tertiary care. It is not PBR excluded so costs will not be recharged to CCGs. NICE does not expect a significant impact on resources. Patients need to have regular ophthalmic examinations, which must be provided by secondary care. The APC agreed to the red statement. ***APC/19/79/05 – Doxylamine/pyridoxine for nausea and vomiting in pregnancy*** CBa went through the details of the green statement. This is the only treatment specifically licensed for the treatment of nausea and vomiting in pregnancy and so a green RAG was proposed by NMSG due to the MHRA prescribing hierarchy guidance. The budget impact information is from the NICE budget impact template; the safety information has been taken from the SPC; a comparison chart of costs for different first-line treatments has been included on page 2; and dosing recommendations are on page 3. One member raised strong concerns about a green RAG rating as the evidence for efficacy is extremely weak and it is expensive, so suggested this should be black instead. AH advised that, based on the evidence alone, the NMSG had reached the same conclusion. However, NICE published an evidence summary that included specific advice from the MHRA regarding the need to justify the use of medicines that do not have a specific license in preference to one with a specific license. It is very difficult not to make the only licensed product available in the context of the MHRA directive and there is an APC precedent for approving medicines where they are the only available licensed option, to make them available as an option. Discussions took place over whether this should be made second-line. The NMSG felt it should be another alternative pharmacological option to be used after conservative management has failed and should not specify first-line or second-line. It was agreed that prescribers should take a number of things into consideration when choosing which option to prescribe for an individual patient; including evidence of efficacy, cost, drug exposure due to daily dosing in pregnancy vs ‘when required’ dosing, adverse effects and license. The APC asked that this is added to the formulary entry for doxylamine/pyridoxine as a reminder for prescribers. It was also acknowledged that if it does not actually work in clinical practice then GPs will not continue to prescribe it. The effect on driving will make it unsuitable for a significant number of patients as well. The APC agreed the green statement subject to the budget impact table from page 1 being moved towards the end of the document, the removal of “until cleared to do so by their healthcare provider” from the last sentence in ‘Patient factors’ and the agreed additional information being added to the formulary entry.	

APC/19/80	**Shared Care**	
	APC/19/80/01 – Apomorphine prescribing support information This is a routine review of an existing document. Two new sections have been added to clarify the responsibilities of the Specialist and responsibilities of the GP. There is now a GP letter. HD outlined the details of the document. Consultation feedback was constructive and has been incorporated into the information. The APC agreed to this prescribing support information and CCGs agreed to their "approvals" being carried over from the original document. ***APC/19/80/02 – Amiodarone prescribing support information*** This is a new document and a proposed RAG change from Amber Initiated to Amber Retained. It has been drafted in response to the new NHSE guidance. There now needs to be an annual review to assess ongoing suitability, so it better fits the amber retained criteria. Regarding eye examinations, the shared care subgroup agreed the SPC should be followed and patients should have an annual ophthalmological review. They would not be able to have annual eye tests with the optician in any case, as NHS eye tests are only performed every two years. The APC agreed to this Prescribing Support Information. ***APC/19/80/03 – Gonadorelin analogues prescribing support information*** One amendment has been made to this document in the second paragraph on the first page to say that the first dose has been administered in secondary care. This has been added for clarity as previously it said that the patient had been started on treatment. The APC agreed to this amendment.	
APC/19/81	**Formulary and Guidelines**	
	APC/19/81/01 – Cinacalcet in PHPT This treatment for primary hyperparathyroidism (PHPT) is commissioned by NHSE therefore it is currently red in the formulary. In the summer, NHSE sent a letter to Trusts saying it could be continued by non-specialist services in secondary or primary care under a shared care arrangement; this would mean that GPs could take on the prescribing. The FGSG had received an application from a Trust to reconsider the RAG rating in light of this. However, it felt it could not progress with examining this further as it is commissioned by NHSE and, if prescribed in primary care, there is no identified mechanism to agree shared care or for NHSE to reimburse the prescribing cost to CCGs. The APC agreed with this position. ***APC/19/81/02 – Rituximab in FSGS*** Disease-modifying therapy for inflammatory renal conditions, primarily refractory focal segmental glomerulosclerosis (FSGS), is NHSE commissioned. NHSE has recently published a commissioning policy specifically stating it does not routinely commission rituximab for this indication. The subgroup had received an application from a Trust for consideration of this but in the light of the above the subgroup recommends that Pan Mersey CCGs should not consider commissioning rituximab for inflammatory renal conditions, primarily FSGS. It was suggested this was annotated as NHSE commissioned and black in the formulary for this indication, to make this clear in future. Applications for	

	funding would need to be submitted to the NHSE IFR process if patients were deemed clinically exceptional. The APC agreed to this proposal. ***APC/19/81/03 – Biologics in psoriasis – use prior to PUVA*** This was discussed by APC at the September meeting in light of consultation feedback. NICE TAs for biologic drugs all state that patients should have tried PUVA first, however, the NICE clinical guideline allows patients to receive biologic treatment without prior PUVA if this isn't possible for patients due to logistical reasons. Different hospitals offered varying clinic times for PUVA, affecting convenience for patients with work commitments, etc. The APC had asked the subgroup to investigate what other areas of the country were doing to address this. The subgroup only had limited responses to this after asking nationally. In one area guideline this is not mentioned but there was informal feedback that it is a recognised issue and if the patient has a genuine reason then they are allowed to progress to a biologic without prior PUVA. The Greater Manchester guideline does not specifically cover this either. On balance, the subgroup felt the pragmatic solution was that patients would be permitted to receive biologic without prior PUVA if there were genuine reasons. Specialists should ensure this is the case. There are many variables affecting cost of allowing this – which biologic, whether biosimilar, patient number estimates and the time / number of courses of PUVA a patient could have, so it is difficult to produce a cost impact and therefore this is very much an estimate. It was suggested adding relevant questions on the Blueteq forms concerned, to say PUVA had been offered and the reason why it was not suitable - this would enable audit to be done to monitor the extent this was happening. It was agreed an audit of this will be carried out in one year's time. The APC agreed the above. ***APC/19/81/04 – Nebulised antibiotics in non-CF bronchiectasis – Amber retained statement*** There has always been some prescribing in primary care, so this information is to support primary care prescribers. These drugs are being used off-label for non-cystic fibrosis bronchiectasis. Feedback was constructive and has been incorporated. HD went through the details. Patient numbers have been collated from all the trusts and there are expected to be around 100 patients per year on colistimethate, 10 on tobramycin and 2-3 on gentamicin. There were no comments or questions and the Amber Retained statement was agreed by the APC. ***APC/19/81/05 – Cyproterone and bicalutamide RAG for prevention of tumour flare*** It was pointed out to the subgroup that these drugs should have a Red RAG rating for the prevention of tumour flare in patients being initiated on a gonadorelin analogue for the treatment of prostate cancer, because the first dose is administered by the Trust. It was noted that there are different arrangements for the initiation of gonadorelin analogues in Warrington and Halton CCGs so the formulary will clearly reflect this. Other indications will remain Amber Initiated. There were no comments or questions and the APC agreed with the Red RAG rating.	**GR**

APC/19/82	**APC Reports**	
	APC/19/82/01 – NICE TA Adherence Checklist October 2019 – FOR NOTING Updated to end of October 2019. This will be uploaded to the Pan Mersey website. ***APC/19/82/02 – RMOC update – FOR NOTING*** The CSU team routinely comment on draft documents that are circulated from individual RMOCs for wider comment. Once the final RMOC publication is available, the CSU team check if it is necessary to review or adapt anything in Pan Mersey. In order to provide assurance that this is happening, it has been proposed that each RMOC final publication is verbally reported to APC with a summary of what the implications are for Pan Mersey. The only publication since the last update is an advisory statement from RMOC Midlands & East for Sodium oxybate in adults. AH confirmed that the RMOC criteria match the Pan Mersey position, with sodium oxybate as last-line option prescribed within a specialist sleep service. However, it should be noted that Pan Mersey commissions Pitolisant as an additional option to be considered before sodium oxybate, which has not been considered by RMOC at this time. <u>RMOC North update:</u> MVM and AH went to the meeting of RMOC North on 6th November. Ongoing discussions appear to show a preference for remaining as a single RMOC North rather than splitting into North West and North East. This is due to the smaller number of STPs in the North of England, as the STPs are larger than elsewhere in the country. Further work needs to be undertaken to establish how best for RMOC to engage with APC/ICS/STP. The expectation is that APC/ICS/STP will have regard to implementation of RMOC advice. It will continue to be a standing agenda item for Pan Mersey. <u>Workstreams of interest</u>: There is more work going on around shared care and agreement of shared care definition and standard templates nationally. It is hoped to also get some high-level national LMC input to ensure appropriate discussions are held around resourcing shared care adequately before rolling the RMOC work out nationally. RMOC North has agreed to shared care by drug rather than by disease, which is in line with the Pan Mersey approach. Work is ongoing around best value biologics and biosimilar adalimumab. A draft position statement on oral vitamin B supplementation in alcoholism is in progress. Datapacks are being developed to assist organisations with benchmarking for Low Priority Prescribing.	
APC/19/83	**Any Other Business**	
	APC/19/83/01 – Andexanet Alfa – funding arrangements pre-NICE Andexanet Alfa has been recently launched in the UK. It is a specific reversal agent for factor Xa inhibitor anticoagulants, licensed for the reversal of apixaban and rivaroxaban. Theoretically, it should also effectively reverse edoxaban but trial data are not available to support this so it is not recommended. It is a PBR-excluded drug, so costs would be recharged to CCGs. The average treatment cost per patient would be	

	around £16,500. Giving blood products is not usually successful for these patients. The NICE TA is not expected until June 2020. Consensus between the CCG Medicines Management Leads and Trust Chief Pharmacists is that it would be inappropriate to wait until the NICE TA is published before making adexanet available to patients. It would take the NMSG 4-5 months to take it through full APC process, which was also felt to be too long and would be putting patients at risk in the meantime. Therefore, it was agreed to progress this outside of the APC process. Dave Thornton is composing a briefing paper for CCGs to consider with a view to commissioning the use of andexanet in very specific situations, to be agreed and defined. APC members will be kept informed of progress. Trust representatives indicated they are keen for this to be available and feel that if there is a product that works then they should be able to use it. The issue of using edoxaban as preferred DOAC was raised in light of there being no licensed reversal agent available. It seemed that Trusts would be looking to use andexanet off-label for any patients on edoxaban presenting with major bleed. It was also agreed that the learning from this situation should be used to develop a process for urgent review to enable NMSG to respond more quickly if a similar situation arises again. ***APC/19/83/02 – APC Chair*** Dr Adit Jain and Peter Johnstone initially agreed to co-chair APC. However, AJ has confirmed that he is willing to be substantive chair for a period of time. Therefore, it was agreed that PJ will now be vice chair, with Dr Anna Hunter remaining as deputy chair.	
APC/19/84	**Date, Time and Venue for the next meeting**	
	Date and time of next APC meeting: The next meeting will be on Wednesday 29 January 2020 at 2.00-4.00pm PLEASE NOTE: THERE IS NO MEETING IN DECEMBER Venue: The Education Centre, Kent Lodge, Broadgreen Hospital, Liverpool, L14 3LB	

The agenda and minutes of this meeting may be made available to public and persons outside of The Pan Mersey Area Prescribing Committee Health Community in order to comply with requests made under the Freedom of Information Act 2000.