Minutes

Meeting	**Pan Mersey Area Prescribing Committee**
Venue	Microsoft Teams online meeting
Date and time	Wednesday 26 May 2021, 2.00-3.00pm

Members		
AL-JAFFAR, Hannah	Southport and Ormskirk Hospital NHS Trust	Y
ATHERTON, Diane	NHS Wirral CCG	Y
BARNETT, Rob Dr	Liverpool Local Medical Committee	N
BARTON, Carolyn	NHS Knowsley CCG	Y
CARTWRIGHT, Nicola	NHS St Helens CCG	Y
CHILTON, Neil	North West Boroughs Healthcare NHS Foundation Trust	Y
COLLINS, Daniel	Liverpool Women's Hospital NHS Foundation Trust	N
CROSBY, John Dr	Mersey Care NHS Foundation Trust	Y
CULLUMBINE, Ann Dr	Wirral Local Medical Committee	Y
DONLON, Kieron	NHS Wirral CCG	Y
DOYLE, Catherine Dr	NHS Warrington CCG	N
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust (Royal)	N
FORDE, Claire Dr	NHS Halton CCG	N
FORREST, Danny	Liverpool Heart and Chest Hospital NHS Foundation Trust	Y
HAWCUTT, Dan Dr	Alder Hey Children's NHS Foundation Trust	N
HENSHAW, Anne	Midlands and Lancashire Commissioning Support Unit	Y
HUNTER, Anna Dr	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
IRVINE, Adam	Cheshire and Merseyside Local Pharmaceutical Committee	Y
ISLAM, Jasmeen	Cheshire and Wirral Partnership NHS FT	N
JAIN, Adit Dr	NHS Knowsley CCG	N
JOHNSTON, Jenny	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
JOHNSTONE, Peter (Chair)	NHS Liverpool CCG	Y

Members		
KNIGHT, Lisa	Wirral Community NHS Foundation Trust	N
LLOYD, Barry	NHS West Lancashire CCG	N
LUNN, Jenny	NHS Warrington CCG	N
LYNCH, Susanne	NHS South Sefton CCG, NHS Southport and Formby CCG	N
McKERRELL, Geraldine	Mersey Care NHS Foundation Trust, Community Services Division	Y
McNULTY, Sid Dr	St Helens and Knowsley Teaching Hospitals NHS Trust	Y
PARKER, James	Warrington and Halton Hospitals NHS Foundation Trust	Y
PAULING, Pamela	Wirral University Teaching Hospital NHS Foundation Trust	Y
PHILLIPS, Kathryn	Bridgewater Community Healthcare NHS Foundation Trust	Y
RAFFERTY, Sarah	Mersey Care NHS Foundation Trust	N
READE, David Dr	NHS St Helens CCG	Y
REID, Lucy	NHS Halton CCG	Y
SANDERSON, Paul	Alder Hey Children's NHS Foundation Trust	Y
SAWERS, Claire	NHS Warrington CCG	Y
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	N
THORNTON, Dave	Liverpool University Hospitals NHS Foundation Trust (Aintree)	Y
THORPE, Bethan	Cheshire and Wirral Partnership NHS FT	Y
WELSBY, Mike	St Helens and Knowsley Teaching Hospitals NHS Trust	N
Non-voting members		
HALL, Gareth	APC lay member	Y
In attendance		
DINGLE, Helen	Midlands and Lancashire Commissioning Support Unit	Y
JAEGER, Emma	Midlands and Lancashire Commissioning Support Unit	Y
MARSDEN, Ashley	North West Medicines Information Centre	Y
MORONEY, Tamsin	Midlands and Lancashire Commissioning Support Unit	Y
WILSON, Paula	Midlands and Lancashire Commissioning Support Unit	Y

1	Welcome and apologies	
	The Chair welcomed members and accepted apologies from the following: Dr Adit Jain, Susanne Lynch (Jenny Johnston attending), John Williams (Hannah Al-Jaffar attending), Dr Claire Forde, Dr Catherine Doyle, Dr Rob Barnett, Mike Welsby, Graham Reader, Nicola Baxter, and Barry Lloyd.	

2	**Declarations of interest and quoracy**	
	A quoracy check confirmed that this meeting was quorate. There were no declarations of interest for items on the agenda.	
3	**Minutes of the last meeting**	
	The Minutes of the APC meeting on 28 April 2021 were agreed to be an accurate record and were ratified. The Minutes of the APC meeting on 24 March 2021 (which were rolled over from the April meeting because it was not quorate) were agreed to be an accurate record of the meeting and were ratified.	
4	**Matters arising**	
	Update on Shared Care bullet point amendment: At the March APC meeting it was agreed that HD would speak to secondary care clinicians to check that the final wording that had been agreed at the meeting was acceptable. Feedback was mixed and inconclusive so the Shared Care Subgroup agreed that the wording should remain as it was. If any problems are recorded as a result of this, the subgroup will discuss again and consider any other ideas or proposals. This was agreed by the APC.	
5	**New medicines**	
5.1	**Bempedoic acid with ezetimibe for treating hypercholesterolaemia – NICE TA694** NICE TA 694 was published on 28 April 2021 and recommends bempedoic acid with ezetimibe as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults, only if certain criteria are met. TM summarised the details of the statement. The TA recommends treatment with either the combination bempedoic acid-ezetimibe product or bempedoic acid and ezetimibe prescribed as separate components. The TA does not recommend bempedoic acid monotherapy without ezetimibe, or in combination with a statin. There is a commercial arrangement which means that bempedoic acid and bempedoic acid-ezetimibe can be prescribed across primary and secondary care, they are not tariff-excluded PbRE drugs. There is a slight cost saving when the combination product is prescribed, rather than prescribing as separate components. It is advised that monitoring of LFTs should be in line with monitoring recommendations for statins and wording has been used from NICE CG18. TM discussed this with Dr Mishra (Consultant Lipidologist) who supported this approach and Dr Mishra advised how bempedoic acid should be dealt with if there is an increase in transaminases over 3 times the upper limit of normal. Local lipid specialists from LUHFT are keen to use this and support GPs prescribing in accordance with the TA. They felt that GPs would be able to initiate, but may require some education on bempedoic acid. The NMSG felt that GPs would be able to initiate this, therefore a green statement was produced. SMc pointed out that on page 2 under “Effectiveness”, it does not say how much LDL-cholesterol was lowered by, but this information was provided for the combination product on page 4. TM to add these details to page 2 for completeness. Subject to these minor additions being made, the APC agreed to the green statement.	TM

5.2	**Andexanet alfa for reversing anticoagulation with DOACs – NICE TA697** NICE TA 697 was published on 12 May 2021 and recommends andexanet alfa as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life threatening or uncontrolled bleeding, only if the bleed is in the gastrointestinal (GI) tract. AH presented the statement. For patients with life threatening or uncontrolled intracranial haemorrhage, NICE recommends the use of andexanet alfa only as part of an ongoing randomised trial mandated by the regulator. NICE does not recommend the use of andexanet for reversing anticoagulation in life-threatening or uncontrolled bleeding in 'other major bleeds' or for reversing anticoagulation in patients taking edoxaban, which is an off-label indication. NICE estimates the cost of implementing this TA as £19,000 per 100,000 population in 2021/22, rising to £48,000 per 100,000 population by 2023/24, calculated using NHS list price. The actual cost of implementing this guidance will be less once the PAS discount is applied. AH reported that, locally, there are concerns in the trusts because it is licensed for all life-threatening or uncontrolled bleeding, not just major GI bleeds. Also, andexanet alfa is not licensed for patients taking edoxaban. SMc asked if it was worth putting in this statement that it is not recommended outside of the NICE TA but the APC is looking into this. However, it was felt that this would not usually be added to statements for NICE TAs. It was suggested that, in the meantime, more local guidance, including advice relating to edoxaban would be helpful. As these are urgent issues, PJ suggested that it should be picked up at the next Chiefs and Leads Meeting on 9th June. The APC approved the red statement.	AH
5.3	**Terminated NICE TAs** When a drug/indication has been horizon scanned onto the NMSG workplan, a grey statement is issued at launch. If the drug and indication is in the NICE Technology Appraisal (TA) work programme, then this grey position will not be reviewed until the NICE TA is published. In the last year there have been three drugs/indications that were in the NICE TA work programme when they were launched in the UK, but subsequently the NICE TA was terminated because the manufacturer did not provide the necessary evidence submission: <u>Ranibizumab for proliferative diabetic retinopathy</u>: NICE is unable to make a recommendation. The company has confirmed that it does not intend to provide an evidence submission for the appraisal because it will not add value. There is unlikely to be sufficient evidence that ranibizumab is a cost-effective use of NHS resources compared with panretinal photocoagulation. <u>Dupilumab for chronic rhinosinusitis with nasal polyps</u>: NICE is unable to make a recommendation. The company has confirmed that it does not intend to provide an evidence submission for the appraisal because there is unlikely to be sufficient evidence that the technology is a cost-effective use of NHS resources in this population.	

	Omalizumab for chronic rhinosinusitis with nasal polyps: NICE is unable to make a recommendation. The company has confirmed that it does not intend to provide an evidence submission for the appraisal because the technology will not be launched in the UK for treating this indication. In circumstances where the NICE TA has been terminated and the manufacturer has confirmed that there is unlikely to be sufficient evidence that using that drug to treat that indication is cost-effective use of NHS resources, or that they do not intend to launch the drug to treat that indication in the UK, the NMSG is of the opinion that they should not look to assess this drug/indication further. The NMSG proposes that the drug for this indication should become BLACK in the formulary, with a link to the terminated NICE TA, and that it would not be reviewed further unless NICE recommences the TA process and a further NICE TA is published. The APC approved this proposal. This will now become the standard process for NMSG to adopt in the situations described above.	
6	**Formulary and Guidelines**	
6.1	**Azithromycin statement** This was a routine review of the existing statement that had been presented at the April APC meeting. At the meeting, it was noted that often, patients will not accept a non-specialist stopping a drug that a specialist has started so their discussions with the consultant should include timescales of when they might expect to stop taking azithromycin, and that the specialist will ask the GP to make the assessment on stopping it if the success criteria are not met. To address this, a template letter for specialists to use has been produced and the statement was amended accordingly to support this change. The APC had previously agreed that it was unnecessary for re-consultation to be carried out as these actions were to support and not change the recommendations in the statement. APC members approved the updated statement and template letter. It was agreed that the existing approvals should be carried over.	
6.2	**Direct oral anticoagulants (DOACs) in VTE statement** This is a full review of the previous statement, and it now follows NICE NG158 (Venous thromboembolic diseases: diagnosis, management, and thrombophilia testing), published in March 2020. The previous statement has already been withdrawn as there have been significant changes including the recommendation to use DOACs for people with active cancer and confirmed proximal DVT or PE. NICE say these new recommendations are expected to lead to increased use of DOACs, particularly apixaban and rivaroxaban, to treat suspected and confirmed VTE. This should reduce the need for resources to monitor INR, manage bleeding complications and administer parenteral anticoagulation. NICE state that this guidance will result in savings for the NHS. The consultation feedback was constructive, and the suggestions have been incorporated into the statement. With reference to the choice of DOAC, members suggested the DOAC of lowest acquisition cost. An additional comment about patients at extremes of	HD

	bodyweight to be added. Subject to that additional comment, the APC approved the statement. It was also agreed that existing approvals may be carried over.	
6.3	**Inflammatory Bowel Disease Guidelines update** This is a minor update to include the use of infliximab for acute exacerbations of ulcerative colitis (see 'additional information' box on page 3). Consultation feedback was in support of the update. In line with feedback received, methotrexate and polymeric diets have been added to the top box in the Crohn's disease pathway. The APC agreed this update. Badges have not yet been added to the top of this pathway as some approvals are still outstanding and the Chair asked if Leads could forward their outstanding approvals. It was agreed that the existing approvals may be carried over.	CCG Leads
7	**Shared Care**	
7.1	**Amiodarone prescribing support information** This was a routine review of the existing prescribing support information, and a new GP letter was produced. Six-monthly U&E monitoring as recommended in the NICE CKS on atrial fibrillation was added to the prescribing support information. The consultation feedback agreed with the documents and provided constructive suggestions to clarify the information in the GP letter which have been incorporated. Two MHRA safety alerts have been added to the interaction section. APC members approved these updated documents. It was agreed that existing approvals may be carried over.	
7.2	**Hydroxychloroquine prescribing support information** This was a review of the existing prescribing support information incorporating additional guidance from the Royal College of Ophthalmology guidelines published in 2020. The GP letter has also been adapted to reflect the updated guidance. The consultation feedback was straightforward. One trust raised some queries which have been addressed, and guidance for dose reduction in renal impairment has been made clearer at the bottom of the first page. The APC approved these updated documents and for the existing approvals to be carried over.	
7.3	**RMOC Shared Care Guidance** The RMOC shared care guidance was published in March 2021 and was discussed by the Shared Care subgroup on 11 May. Previously, the Shared Care subgroup submitted comprehensive feedback to an earlier draft of the document and, as a result, RMOC recommends that guidance should be developed by drug rather than by indication. This reflects Pan Mersey practice. However, because the RMOC definition of shared care encompasses the Pan Mersey Purple and Amber Retained RAG definitions and there are significant differences from section 6 onwards, the subgroup recommends that the document should not be adopted as it stands. It is, however, a useful document, and the subgroup will definitely adopt some of the content in the appendices into Pan Mersey shared care documents.	

	The subgroup proposed that the Pan Mersey shared care frameworks should be reviewed, and the following action taken: ▪ Section 6.1 Patient roles and responsibilities will be added to Pan Mersey documents. ▪ Section 6.2 Specialist roles and responsibilities – some of these points will be added. ▪ Section 6.3 Primary Care roles and responsibilities – some of these points will be added. ▪ Section 6.4 Community Pharmacy roles and responsibilities will be added to the documents. ▪ Appendix 1 includes two drugs that are Red in Pan Mersey: dronedarone and hydroxycarbamide. Both have been reviewed by the shared care subgroup and APC, so the subgroup does not propose a change for these at present. ▪ Appendix 2 onwards are letters which will be reviewed at the July subgroup meeting to consider if they should be adopted. ▪ Appendix 5 is the shared care framework template and will be reviewed at the July subgroup meeting. AI asked about community pharmacies. What happens if a Pan Mersey GP prescribes something and then the patient goes to a pharmacy outside Pan Mersey, is that a problem? HD will put this on the July Shared Care meeting agenda for discussion. DF asked about dronedarone. HD informed the meeting that there is a draft RMOC dronedarone document out for consultation and, in that document, they are proposing that all the ECGs are carried out in secondary care. This means the prescribing and monitoring is being split which is potentially unsafe. Last time the SCSG reviewed dronedarone to try to achieve a purple RAG rating, it could not be done across Pan Mersey as not all CCGs could access interpreted ECGs in primary care. At the point when the RMOC shared care frameworks are published, there will be a formal review of the Pan Mersey position. The APC agreed to the proposal, not to adopt the document as a whole, but to adopt the sections that would be useful.	HD
8	**Safety**	
8.1	**CLOZAPINE: reducing the risk of harm** This is a new document developed following a MHRA Drug Safety Update published in October 2017, highlighting the potentially fatal risk of intestinal obstruction. Mental health trust representatives from the safety subgroup collaborated to develop the content to support best practice and help mitigate the risks associated with clozapine therapy. The APC approved this document.	
9	**APC reports**	
9.1	**NICE TA Adherence Checklist (April 2021) – for noting** Pan Mersey APC is compliant up to the end of April 2021. The report will be uploaded to the APC website.	

9.2	**RMOC update** Buprenorphine long-acting injection guidance was published on 23 April 2021. The Formulary and Guidelines Subgroup will consider the guidance and report back their recommendations to the next APC. The first four of the RMOC shared care frameworks are currently out for consultation. The shared care subgroup is reviewing the documents and supplying the formal response to RMOC. All comments will be collated and submitted under the banner of Pan Mersey. For clarity, AH explained that RMOC guidance is not mandatory, but APC are required to give it due consideration.	
10	**Any other business**	
10.1	Appeal: AH informed the APC that a local appeal has been received regarding the Amber Initiated RAG rating for dapagliflozin for heart failure. The TA states that dapagliflozin should be started on the advice of a HF specialist, which would fit Amber Recommended. NMSG has started to consider the appeal and currently has a draft Amber Recommended statement out for consultation, the results of that will be part of the reply to the appeal.	
11	**Next meeting**	
	Wednesday 23 June 2021 at 2.00 to 3.30 pm. NOTE: the next meeting will be 1.5 hours in duration. Online meeting via Microsoft Teams	