Minutes

Meeting	**Pan Mersey Area Prescribing Committee**
Venue	Microsoft Teams online meeting
Date and time	Wednesday 23 March 2022, 2.00-4.00pm

Members	Organisation	Present
AL-JAFFAR, Hannah	Southport and Ormskirk Hospital NHS Trust	Y
ATHERTON, Diane Dr	NHS Wirral CCG	N
AZAR, Mo	Alder Hey Children's NHS Foundation Trust	N
BARK-JONES, Jo	Bridgewater Community Healthcare NHS FT	Y
BARTON, Carolyn	NHS Knowsley CCG	Y
BIRCHALL, Becky	NHS Halton CCG	Y
CARTWRIGHT, Nicola	NHS St Helens CCG	Y
CHARLTON, Marianne	Wirral University Teaching Hospital NHS Foundation Trust	Y
CHEUNG, Jimmy	Bridgewater Community Healthcare NHS Foundation Trust	N
CHILTON, Neil	Mersey Care NHS Foundation Trust	N
CROSBY, John Dr	Mersey Care NHS Foundation Trust	N
DONLON, Kieron	NHS Wirral CCG	Y
DOYLE, Catherine Dr	NHS Warrington CCG	Y
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust	N
FORDE, Claire Dr	NHS Halton CCG	Y
FORREST, Danny	Liverpool Heart and Chest Hospital NHS Foundation Trust	N
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	N
JAIN, Adit Dr (Chair)	NHS Knowsley CCG	Y
JOHNSTON, Jenny	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
JOHNSTONE, Peter	NHS Liverpool CCG	Y

Members	Organisation	Present
KNIGHT, Lisa	Wirral Community Health and Care NHS Foundation Trust	N
LLOYD, Barry	NHS West Lancashire CCG	Y
LUNN, Jenny	NHS Warrington CCG	Y
LYNCH, Susanne	NHS South Sefton CCG, NHS Southport and Formby CCG	N
McKERRELL, Geraldine	Mersey Care NHS FT, 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	N
PHILLIPS, Kathryn	Bridgewater Community Healthcare NHS Foundation Trust	N
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	Y
THORNTON, Dave	Liverpool University Hospitals NHS Foundation Trust (Aintree)	N
VAN MIERT, Matthew Dr	Wirral University Teaching Hospital NHS Foundation Trust	N
WELSBY, Mike	St Helens and Knowsley Teaching Hospitals NHS Trust	N
WILLIAMS, John	Southport and Ormskirk Hospital NHS Trust	N
Non-voting members		
BARNETT, Rob Dr	Liverpool Local Medical Committee	Y
CAMPHOR, Ivan Dr	Mid-Mersey Local Medical Committee	N
CULLUMBINE, Ann Dr	Wirral Local Medical Committee	Y
HALL, Gareth	APC lay member	Y
IRVINE, Adam	Cheshire and Merseyside Local Pharmaceutical Committee	N
In attendance		
DINGLE, Helen	Midlands and Lancashire Commissioning Support Unit	Y
MARSDEN, Ashley	North West Medicines Information Centre	Y
MORONEY, Tamsin	Midlands and Lancashire Commissioning Support Unit	Y
READER, Graham	Midlands and Lancashire Commissioning Support Unit	Y

1	**Welcome and apologies**	
	The Chair welcomed members. Apologies were accepted from Dr David Reade, Susanne Lynch (Jenny Johnston attending), Adam Irvine, Mike Welsby, and James Parker.	

2	**Declarations of interest and quoracy**	
	There were no declarations of interest for items on the agenda. A quoracy check confirmed that this meeting was not quorate.	
3	**Minutes of the last meeting**	
	The Minutes of the APC meeting on 23 February 2022 were agreed to be an accurate record of the meeting but, because this meeting is not quorate, the minutes will be brought to the next APC meeting to be formally ratified.	VZ
4	**Matters arising**	
	There were no matters arising.	
5	**New Medicines**	
5.1	**Grey statement summary – for noting** The following grey 'holding' statement has been produced for the APC website: TOFACITINIB film-coated tablets (XELJANZ®▼) for Ankylosing spondylitis: To be reviewed when the NICE TA is published, currently expected 22 August 2022. This was noted by the APC.	
5.2	**Fremanezumab for migraine prevention – NICE TA764** NICE reviewed TA631, fremanezumab for migraine prevention, and published the update as TA764 in February 2022, which recommends fremanezumab for prevention of chronic migraine and episodic migraine, provided specific criteria are met and the company provides it according to the commercial arrangement. TA631 previously only recommended fremanezumab for chronic migraine. This is a PbRE (tariff-excluded) high-cost drug and is specialist only, therefore a red statement has been produced. NICE does not expect implementing this TA to have a significant impact on resources, because fremanezumab is a further treatment option for episodic migraine and the overall cost of treatment will be similar to other treatment options. The resource impact assumptions made by NICE are unchanged for both chronic and episodic migraine. The existing red statement for TA631 will be superseded by this red statement. The APC approved this statement.	
5.3	**Dapagliflozin for chronic kidney disease – NICE TA775** NICE TA775 was published on 09 March 2022 and recommends dapagliflozin as an option for treating chronic kidney disease (CKD) in adults, provided that specific criteria are met. Dapagliflozin is recommended as an add-on to optimised standard care including the highest tolerated licensed dose of ACE inhibitors or angiotensin-receptor blockers, unless these are contraindicated, in people with an eGFR of 25 mL/min to 75 mL/min at the start of treatment and who have type 2 diabetes mellitus or have a urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more.	

	A green RAG rating was assigned by NMSG as it was agreed that these patients would not be under the care of a renal specialist at this stage of CKD. Although dapagliflozin has an amber RAG for use in heart failure, this was not felt to be appropriate for CKD as it would create a barrier to accessing treatment. Patients would need to wait for a referral to nephrology, who don't usually see this cohort of patients, whereas HF patients would already be under the specialist team at the point where dapagliflozin is indicated. It was also noted that the NICE TA for use in heart failure specifies that treatment requires specialist advice and there is no mention of this in the TA for CKD. Costs are from the NICE resource impact report, which takes into account the potential resources released from delayed disease progression. A question was raised about who would counsel the patient on DKA risk and PS confirmed that it is the responsibility of the initiating prescriber. It was noted that dapagliflozin is contraindicated for use in type 1 diabetes, and it was queried whether the contraindication applies just for glycaemic control or for treatment of heart failure and CKD. PS confirmed that dapagliflozin should not be used in type 1 diabetes, and patients with type 1 diabetes should not be prescribed dapagliflozin for CKD. There is an MHRA safety alert regarding use of dapagliflozin in patients with type 1 diabetes and it is no longer licensed in type 1 diabetes. AJ confirmed that an alert is generated by EMIS, but it is a warning for eGFR not DKA, and that a DKA alert comes up on OptimiseRx, which would trigger a reminder to the prescriber, which was also confirmed by PJ. The APC approved this statement.	
5.4	**Solriamfetol for obstructive sleep apnoea (OSA) – NICE TA777** NICE TA777 was published on 09 March 2022 and does not recommend solriamfetol for treating adults with excessive daytime sleepiness caused by obstructive sleep apnoea (OSA). NICE states that the trial evidence does not show an improvement in quality of life. There are also concerns about how the trial data has been used in the economic model. Therefore, the cost-effectiveness estimates for solriamfetol compared with standard care alone are uncertain and they are likely to be higher than what NICE normally considers an acceptable use of NHS resources. Consequently, solriamfetol is not recommended by NICE for OSA and a black statement has been produced. The APC approved this statement.	
5.5	**Doxylamine/pyridoxine for nausea and vomiting in pregnancy – Routine review at expiry, for inclusion on the static list** Routine review of existing green statement at expiry, for inclusion on the Static List. No significant changes have been made to the document. Minor updates are highlighted in yellow and are in accordance with updated NICE NG201 and the SPC. Costs have also been updated. These updates do not change the RAG rating of doxylamine / pyridoxine, which remains an option for prescribing. Stakeholder feedback queried the positioning of doxylamine / pyridoxine compared to other treatments. The statement does not make any recommendations regarding the position of doxylamine / pyridoxine and highlights the importance of shared decision making with the patient. Doxylamine / pyridoxine is a licensed product and is available as	

	an option if a prescriber and patient wish to use it. The NMSG did not feel that the feedback received should change the APC position as there is no new evidence. The APC approved this statement for inclusion on the static list. It was agreed that existing CCG approvals could be carried over.	
5.6	**Expiry extension of documents – Formulary and Guidelines Subgroup, New Medicines Subgroup and Shared Care Subgroup** A list was included in the agenda, of documents that have recently passed their review-by date or will pass their review-by date in the near future. **FGSG:** The FGSG proposes an extension to each review-by date by 1 year, as major changes are thought to be unlikely. This would be reviewed on a case-by-case basis should significant developments occur. **NMSG:** ESKETAMINE nasal spray solution (Spravato®▼) for treatment-resistant depression: NICE paused the appraisal during COVID-19, but progress has since resumed, although the TA publication date remains TBC. The NMSG proposes that the expiry date of the Grey statement is extended by 12 months to allow additional time for the NICE TA to be published. **SCSG:** The Shared Care subgroup proposes that one shared care framework and three prescribing support documents, that will pass their review-by date before May 2022, could be considered for an extension of a review-by date to November 2022 to allow the subgroup to complete its review. The APC confirmed their agreement to these proposals.	
6	**Formulary and Guidelines**	
6.1	**Guideline - testosterone gel for testosterone deficiency in women** This guideline proposes an amber recommended RAG for testosterone gel for testosterone deficiency in women, in line with testosterone use in men, and provides background information and process whereby a specialist assesses patients, optimises other HRT, and then requests primary care to commence prescribing. There is no biochemical / plasma level monitoring required. The use of testosterone gel in women is an off-label indication but testosterone is suggested as an option in NICE NG23 and NICE CKS on menopause. There were some suggestions from primary care clinicians that this could be designated a green RAG as a proportion of GPs are familiar with its use and requirement for specialist involvement may cause capacity issues. However, the subgroup view is amber recommended is appropriate currently, due to the off-label status, but the RAG designation can be reviewed if this changes. Any local community gynaecology services would be included in the definition of specialist for recommendation purposes. This is an area of increasing interest and GPs are being asked to prescribe testosterone for women. Views were expressed that other treatments are used in primary care off-label, and this is acceptable if there is a discussion with the patient about this first. There was some support for a green designation, but it was also pointed out that other GPs may not feel confident to initiate this and there was nothing in the amber recommended designation that prevented GPs initiating therapy if they are competent to do so.	HAJ/ GR

	There was a discussion regarding the language of the guideline, which appeared slightly imprecise in style in places, although it was noted a proportion was taken directly from the British Menopause Society guidance on testosterone replacement. It was agreed that clinical response to therapy is patient-specific and based on an individual's symptom improvement rather than quantitative outcomes. The APC agreed with the proposal to add the use in women to the formulary with amber recommended designation and the overall substance of the guideline, but it was agreed that the subgroup would amend the language style to some passages in the guideline, distinguish between likely side-effects and those arising from any abuse, information on monitoring of safety, mention it is a schedule 4 controlled drug and highlight it is an off-label use and bring the guideline back to the next meeting. As the guideline was agreed in principle it was therefore decided that this would not need to go out for consultation again prior to re-submission to APC.	
6.2	**Dacepton® (apomorphine) injection addition to formulary** The FGSG proposed the addition of the Dacepton® brand of apomorphine hydrochloride to the formulary in addition to the currently included Apo-go® brand. Dacepton® infusion device was felt to be more user-friendly, and it is cheaper than APO-go®, especially when used at lower doses due to the longer expiry of the product. Using the homecare route provides further savings. To mitigate the risk of confusion with having two brands of apomorphine available, it should be prescribed by brand name. There was some Trust consultation feedback regarding potential confusion between brands if both are in use. However, it is not possible to use the incorrect infusion preparation in either of the two brand's infusion systems, patient numbers are low so general ward staff would usually have to learn to use whichever system the patient was using, and the manufacturer provides equivalent user support and helpline advice as is available for Apo-go®. After a discussion of these points, the APC agreed to the addition of Dacepton® to the formulary.	
7	**Shared Care**	
7.1	**Disease-modifying drugs shared care frameworks** This is a routine review of the seven disease-modifying drugs (DMD) shared care frameworks. The review incorporated parts of the RMOC DMD shared care protocols where appropriate, the latest safety guidance, changes in the summaries of product characteristics, and other guidance. The consultation feedback raised a number of queries all of which have been addressed. Most of the suggestions for changes have been incorporated although the subgroup did not agree changes to timescales previously agreed at APC and the request for a further off-label indication for mycophenolate. The shared care subgroup raised a query about the administration of the pneumococcal vaccine for high-risk patients prior to starting DMD therapy. They wondered if it would be better for the patient to receive this in secondary care when the decision to start therapy is made. Trusts have confirmed that they do not have the infrastructure in place to do this. GP practices are covered financially if they enter the READ code 'requires pneumococcal vaccine' and are also supported via the pneumococcal vaccine PGD. For now, the frameworks simply say that high-risk patients should receive the vaccine without	

	specifying where this is done but CCG Leads agreed that this could be looked into further, for the benefit of patients, possibly by being piloted in one trust in the future. APC members approved the updated DMD shared care frameworks and for the existing CCG approvals to be carried over.	
7.2	**Lithium shared care framework** A routine review of the shared care framework was conducted jointly by Cheshire and Wirral Partnership and Mersey Care. This review incorporated parts of the RMOC lithium shared care protocol where appropriate and the latest NICE guidance. Stakeholder feedback was constructive and supportive. All the feedback has been addressed and the documents updated with the suggested changes. A comment about implementation has been noted but is outside the scope of this shared care framework. The Mersey Care representative sent a query to Medicines Information to clarify whether the warning about paternal exposure to lithium reduced fertility or posed a teratogenic risk and are still awaiting their reply. The APC approved the updated lithium shared care framework and for the existing CCG approvals to be carried over.	
8	**Safety**	
8.1	**Summary Care Record: Minimising Harm from Missing Data** This was a routine review at the expiry date. The core advice remains the same. The document includes a new alert to advise the summary care record is not updated for people with temporary registrations. A new recommendation has been added to ensure patients are aware that 'medication prescribed elsewhere' will be shared on the summary care record unless they have opted out. This recommendation followed concerns from the consultation feedback about listing potentially sensitive medication and reciprocates advice from the National Aids Trust and the British HIV association who recommend patients with a summary care record should check that their HIV drugs are included. A question was raised about why confidential information is deemed sensitive in certain conditions, e.g., is an exception being made for HIV? It was not so much of an exception but taken into consideration as a yardstick. It is better to recommend that people are informed that their medications are on the records. It will apply to all people not just a particular cohort of patients. There is the option to opt-out if the patient wishes. RB pointed out that HIV is one of four things that are excluded when sharing records, as a matter of course. Patients have the right to have their records coded so their condition is not obvious. The APC approved this updated document.	
9	**APC reports**	
9.1	**NICE TA Adherence Checklist (February 2022) – for noting** Pan Mersey APC is compliant up to the end of February 2022. The report will be uploaded to the APC website.	

10	**Any other business**	
10.1	RB asked about resuming face-to-face APC meetings or a hybrid meeting with the option of attending in person or dialling in via Teams. MLCSU, as an organisation, is not routinely returning to office spaces yet and it is difficult to find a room large enough for all APC members. There is the additional time-cost of driving to meetings and taking people out of clinical practice that needs to be taken into consideration also. Resumption of in-person meetings is not happening imminently, but due consideration will be given to all options.	
11	**Next meeting**	
	Wednesday 27 April 2022 at 2.00 – 4.00 pm Online meeting via Microsoft Teams.	