

# Minutes

<b>Meeting</b>	<b>Pan Mersey Area Prescribing Committee</b>
<b>Venue</b>	Microsoft Teams online meeting
<b>Date and time</b>	Wednesday 24 November 2021, 2.00-4.00pm

<b>Members</b>	<b>Organisation</b>	<b>Present</b>
ATHERTON, Diane Dr	NHS Wirral CCG	Y
AZAR, Mo	Alder Hey Children's NHS Foundation Trust	Y
BARTON, Carolyn	NHS Knowsley CCG	N
CARTWRIGHT, Nicola	NHS St Helens CCG	Y
CHILTON, Neil	Mersey Care NHS Foundation Trust	Y
CROSBY, John Dr	Mersey Care NHS Foundation Trust	Y
DONLON, Kieron	NHS Wirral CCG	Y
DOYLE, Catherine Dr	NHS Warrington CCG	Y
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust	Y
FORDE, Claire Dr	NHS Halton CCG	N
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	N
HUNTER, Anna Dr	NHS South Sefton CCG, NHS Southport and Formby CCG	Y
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
KNIGHT, Lisa	Wirral Community Health and Care NHS Foundation Trust	Y
LLOYD, Barry	NHS West Lancashire CCG	Y
LOI, Annie	NHS Knowsley CCG	Y
LUNN, Jenny	NHS Warrington CCG	Y
LYNCH, Susanne	NHS South Sefton CCG, NHS Southport and Formby CCG	N

<b>Members</b>	<b>Organisation</b>	<b>Present</b>
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	Y
PAULING, Pamela	Wirral University Teaching Hospital NHS Foundation Trust	Y
PHILLIPS, Kathryn	Bridgewater Community Healthcare NHS Foundation Trust	Y
READER, Graham	Midlands and Lancashire Commissioning Support Unit	Y
REID, Lucy	NHS Halton CCG	Y
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	Y
THORNTON, Dave	Liverpool University Hospitals NHS Foundation Trust (Aintree)	Y
VINCENT, Marc	Liverpool Heart and Chest Hospital NHS Foundation Trust	Y
WELSBY, Mike	St Helens and Knowsley Teaching Hospitals NHS Trust	Y
WILLIAMS, John	Southport and Ormskirk Hospital NHS Trust	N
<b>Non-voting members</b>		
BARNETT, Rob Dr	Liverpool Local Medical Committee	N
CAMPBOR, 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	Y
<b>In attendance</b>		
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	N
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. Apologies were accepted from: Dr Claire Forde, Susanne Lynch (Jenny Johnston attending), Ashley Marsden, John Williams, and Anne Henshaw.

<b>2</b>	<b>Declarations of interest and quoracy</b>	
	There were no declarations of interest for items on the agenda. A quoracy check confirmed that this meeting was quorate.	
<b>3</b>	<b>Minutes of the last meeting</b>	
	Attention was drawn to an amendment made to item 6.2 on page 6 (highlighted in yellow for members). This amendment was agreed. The Minutes of the APC meeting on 27 October 2021 were agreed to be an accurate record of the meeting and formally ratified.	
<b>4</b>	<b>Matters arising</b>	
	None.	
<b>5</b>	<b>New medicines</b>	
5.1	<p><b>Grey statement summary – for noting</b></p> <p>The following 2 grey ‘holding’ statements have been produced for the APC website:</p> <p><u>ABROCITINIB for moderate to severe atopic dermatitis in adults and adolescents aged <math>\geq 12</math> years</u>: Will be reviewed when the NICE TA is published (currently TBC).</p> <p><u>MOMETASONE / OLOPATADINE for moderate to severe nasal symptoms associated with allergic rhinitis in adults and adolescents aged <math>\geq 12</math> years</u>: To be reviewed if a formal application for use is received and prioritised for in-year review.</p> <p>No questions or comments were raised. The above was noted by the APC.</p>	
5.2	<p><b>Upadacitinib for moderate rheumatoid arthritis – NICE TA744</b></p> <p>NICE TA744 was published on 10 November 2021 and recommends upadacitinib either with methotrexate or as monotherapy when methotrexate is contraindicated or not tolerated, as an option for treating moderate active rheumatoid arthritis in adults whose disease has responded inadequately to intensive therapy with two or more conventional disease-modifying antirheumatic drugs, only when specific criteria are met.</p> <p>This is a PbRE (tariff-excluded) high-cost drug and is specialist only, therefore a red statement has been produced. NICE does not expect this guidance to have a significant resource impact as upadacitinib is a further treatment option which is available at a similar price to current treatment options. Localised costs for this TA will be provided in the APC report.</p> <p>No questions or comments were raised. The red statement was approved by the APC.</p>	
5.3	<p><b>Dapagliflozin for symptomatic chronic heart failure with reduced ejection fraction – appeal against APC RAG status</b></p> <p>TM introduced this item and provided a summary. Following publication of NICE TA679 in February 2021, the NMSG proposed an amber initiated RAG on the grounds of the need</p>	

for patient counselling regarding DKA and co-ordinating heart failure and diabetes care when initiating treatment, and the APC approved this in March 2021.

A formal appeal was received on 14 May 2021 against the amber initiated RAG. The grounds for appeal against the RAG rating are that NICE TA679 states: "Start treatment of symptomatic heart failure with reduced ejection fraction with dapagliflozin on the advice of a heart failure specialist" and so the requirement for the specialist to initiate and stabilise treatment with dapagliflozin puts additional barriers in place that restrict patient access to a NICE TA drug.

In response to the appeal, NMSG subsequently reconsidered and reconsulted on an amber recommended RAG on the basis that they felt it was within GP competence to initiate prescribing of dapagliflozin once the specialist has established that the patient is suitable for dapagliflozin. The revised amber recommended statement was brought to the APC meeting on 28 July 2021. However, due to the considerable patient safety concerns from both primary and secondary care clinicians, the appeal wasn't upheld.

Following the result of the appeal and discussion at the July 2021 APC meeting, a Task and Finish group from primary/secondary/tertiary care was set up to produce a pathway and develop prescribing support documents to assist with a safe transfer to amber recommended RAG. Marc Vincent of LHCH explained that the Task and Finish group met twice to put these together. The updated statement and supporting documents were sent out on 'fast-track' consultation in October 2021 and brought back to the NMSG meeting in November 2021. The key updates to the previous draft amber recommended statement are highlighted.

MV gave a summary of the feedback received and the responses. Feedback from primary care remained mixed and a concern was raised from one Trust. Since this statement was initially produced, the license has been withdrawn for dapagliflozin for use in type 1 diabetes, therefore the statement has been updated to clarify that it should not be used for patients with type 1 diabetes. MV went through each of the amendments made. A pre-prescribing checklist has also been added which prescribers might find useful.

AJ welcomed the support documents and highlighted the importance of using the GP communication letter, but asked what assurance can be provided to primary care to ensure that they are always used. MV advised that the Task and Finish group had a wide membership which should assist implementation of the supporting documents, and confirmed that he is looking at whether these documents could be taken through the Cardiac Network Pharmacy Forum for adoption.

MV explained that there is a Cardiac Network position statement regarding dapagliflozin for heart failure, which didn't fully align with the position in Pan Mersey. In light of the discrepancy, it was noted that there did not appear to have been a retraction of the position statement and MV agreed to feed this back to the Cardiac Network.

TM explained that the supporting documents developed through the Task and Finish Group will be housed on the Pan Mersey APC website. A DKA patient alert card has been developed and TM asked how GPs would print this and whether any issues would be expected. AJ advised that it would be useful to utilise e-technology for patients to access on their devices, or that the cards should be printed centrally by CCGs and distributed to GP practices.

MV



	<p>The APC approved the change from amber initiated to amber recommended RAG status, the amber recommended statement, and the supporting documents.</p> <p>Although the formal appeal decision was provided following the APC meeting on 28 July 2021, the appellant will be informed of the outcome from today's meeting.</p>	TM
5.4	<p><b>Andexanet alfa for reversing anticoagulation – addition of off-label use of edoxaban to existing statement</b></p> <p>The existing red statement for use of andexanet alfa for anticoagulant reversal for apixaban and rivaroxaban in accordance with NICE TA697 has been updated to include off-label use as anticoagulant reversal for edoxaban using the same criteria as NICE TA697. This additional usage ensures that patients offered edoxaban have a reversal agent available and will assist the Health and Care Partnership workstream on preferred DOAC.</p> <p>The changes to the current APC document are shown as tracked changes. Preliminary evidence to support use of edoxaban has also been included. This went for fast-track consultation in October and was brought back to NMSG in November. Enquiries suggest that Pan Mersey is the only area that is looking to use andexanet alfa outside of NICE at present. The cost per course, per patient, is approximately £15,000; the PAS price would not apply to this off-label use as it is outside NICE recommendations. With regards to cost impact, MW pointed out that it is anticipated that it will be used very infrequently and has not been used at all at LUHFT for this indication yet. If stock goes out of date, it is understood that the company will reimburse the trust for the expired stock. LUHFT did not feed back in the consultation, but DT confirmed that the trust had already adopted this use internally, prior to taking it through APC.</p> <p>The APC confirmed their approval with a majority vote.</p>	
5.5	<p><b>Dapagliflozin with insulin for treating type 1 diabetes – withdrawal of license extension and NICE TA597</b></p> <p>Following the withdrawal of the license for dapagliflozin for use in type 1 diabetes and subsequent withdrawal of NICE TA 597, the Pan Mersey APC amber initiated prescribing statement for this indication was withdrawn from the website on 12 November 2021 and is no longer accessible. The formulary entry has also been updated.</p> <p>The prescribing statement is now under review and will be brought to the next New Medicines Subgroup meeting on 10 December 2021.</p> <p>This item is for information only.</p>	
5.6	<p><b>Non-renewal of NMSG statements</b></p> <p>The NMSG recommends the non-renewal of the following Pan Mersey APC prescribing policy statements at expiry, in line with previously agreed precedents. The NMSG considers that the NICE TA recommendations for the following 4 drugs are now established into clinical practice and the associated policy statements do not add any further additional benefit. The NMSG proposes that the statements are archived at expiry and the links to the NICE TAs will be retained in the relevant formulary entries:</p> <ol style="list-style-type: none"> <li>1. BOTULINUM NEUROTOXIN TYPE A injection (Xeomin®) for chronic sialorrhoea.</li> </ol>	

	<p>2. PENTOSAN POLYSULFATE SODIUM capsules (Elmiron®) for treating bladder pain syndrome.</p> <p>3. LUSUTROMBOPAG tablets (Mulpleo®▼) for treating severe thrombocytopenia in adults with chronic liver disease having planned invasive procedures.</p> <p>4. PATIROMER powder for oral suspension (Veltassa®▼) for emergency treatment of hyperkalaemia.</p> <p>A Grey statement was issued for DIENOGEST tablets (Zalkya®▼) for endometriosis, and no expression of interest has been received within 2 years, therefore the NMSG proposes that the Grey statement will be archived, and the drug remain as Grey in the formulary.</p> <p>The APC confirmed their agreement to the above.</p>	
<h2>6 Formulary and Guidelines</h2>		
6.1	<p><b>Guidelines for Managing Malnutrition in Adults in the Community - amendment</b></p> <p>The FGSG has made an amendment to Appendix 4 of the guideline, to clarify that contact with the free online “direct to patient sample services” provided by manufacturers can only be made by health care professionals.</p> <p>The APC confirmed its approval.</p>	
6.2	<p><b>Minor Formulary Updates</b></p> <ul style="list-style-type: none"> <li>- <u>Risankizumab 150mg pen</u>: the FGSG proposed replacing risankizumab 75 mg x 2 pre-filled syringe, on the formulary, with 150 mg pen and 150 mg pre-filled syringe. The dose is 150mg and the 150mg pen and syringe allow this to be administered as a single injection. The 2 x 75mg will be discontinued in January 2022. The confidential NHS Patient Access Scheme (PAS) price per dose remains unchanged.</li> <li>- <u>Exenatide 2mg BCise pen</u>: The FGSG proposed the replacement on the formulary of exenatide 2 mg powder and solvent for prolonged-release suspension, with the exenatide 2mg BCise pen prolonged-release injectable suspension. Exenatide 2 mg powder and solvent for prolonged-release suspension for injection in pre-filled pen (exenatide once-weekly) is discontinued. BCise pen is the same cost as powder and solvent for prolonged-release suspension.</li> <li>- <u>Tofacitinib 11mg m/r</u>: The subgroup proposed the addition of Tofacitinib 11mg m/r once daily tablets to the formulary, in addition to 5mg twice daily tablets, for treatment of rheumatoid arthritis and psoriatic arthritis. Tofacitinib 11mg m/r has the same patient access scheme (PAS) and is the same cost as tofacitinib 5mg twice daily, and that this will be in situ as long as the PAS for the 5mg tablets.</li> </ul> <p>The APC approved the above minor amendments to formulary.</p>	
<h2>7 Shared Care</h2>		
7.1	<p><b>Prescribing support information – expiry extension</b></p> <p>The Shared Care subgroup proposed that the following five prescribing support information documents that will pass their review-by date before January 2022, could be considered for an extension of a review-by date to May 2022, to allow the subgroup to complete the reviews.</p>	

	<ul style="list-style-type: none"> <li>▪ Glyceryl trinitrate patches for children</li> <li>▪ Nitrazepam for children</li> <li>▪ Dementia</li> <li>▪ Atypical antipsychotics</li> <li>▪ Methadone</li> </ul> <p>The APC confirmed their approval.</p>	
<b>8</b>	<b>APC reports</b>	
8.1	<p><b>NICE TA Adherence Checklist (October 2021) – for noting</b></p> <p>Pan Mersey APC is compliant up to the end of October 2021. The report will be uploaded to the APC website.</p>	
8.2	<p><b>RMOC update</b></p> <p>RMOC consultation number 6, for the shared care frameworks, is currently underway. It will be submitted to RMOC in December. This is the last of the Shared Care Frameworks consultations. There have been no more RMOC meetings since the last APC meeting.</p>	
<b>9</b>	<b>Any other business</b>	
	None.	
<b>10</b>	<b>Next meeting</b>	
	<p><b>THERE IS NO APC MEETING IN DECEMBER</b></p> <p>Wednesday 26 January 2022 at 2.00 – 4.00 pm</p> <p>Online meeting via Microsoft Teams.</p>	