



Minutes

Meeting	Pan Mersey Area Prescribing Committee
Venue	Microsoft Teams online meeting
Date and time	Wednesday 27 July 2022, 2.00-4.00pm

Members	Organisation	Present
AL-JAFFAR, Hannah	Southport and Ormskirk Hospital NHS Trust	Y
ATHERTON, Diane Dr	NHS Cheshire and Merseyside, Wirral Place	N
AZAR, Mo	Alder Hey Children's NHS Foundation Trust	N
BARK-JONES, Jo	Bridgewater Community Healthcare NHS Foundation Trust	Y
BARTON, Carolyn	NHS Cheshire and Merseyside, Knowsley Place	Υ
BIRCHALL, Becky	NHS Cheshire and Merseyside, Halton Place	Y
CARTWRIGHT, Nicola	NHS Cheshire and Merseyside, St Helens Place	Y
CHARLTON, Marianne	Wirral University Teaching Hospital NHS Foundation Trust	N
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	Y
DOYLE, Catherine Dr	NHS Cheshire and Merseyside, Warrington Place	Y
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust	N
FORDE, Claire Dr	NHS Cheshire and Merseyside, Halton Place	N
FORREST, Danny	Liverpool Heart and Chest Hospital NHS Foundation Trust	N
GILLESPIE-GREENE, Donna	NHS Cheshire and Merseyside, Wirral Place	Y
HAWCUTT, Dan Dr	Alder Hey Children's NHS Foundation Trust	N
HENSHAW, Anne	Midlands and Lancashire Commissioning Support Unit	Y
HUGHES, Rhiannon	Wirral University Teaching Hospital NHS Foundation Trust	Y
HUNTER, Anna Dr	NHS Cheshire and Merseyside, Sefton Place	N
JAIN, Adit Dr	NHS Cheshire and Merseyside, Knowsley Place	N

Members	Organisation	Present
JOHNSTON, Jennifer	NHS Cheshire and Merseyside, Sefton Place	Υ
JOHNSTONE, Peter (Chair)	NHS Cheshire and Merseyside, Liverpool Place	Y
KNIGHT, Lisa	Wirral Community Health and Care NHS Foundation Trust	N
LLOYD, Barry	NHS Lancashire and South Cumbria, West Lancashire Place	Y
LUNN, Jenny	NHS Cheshire and Merseyside, Warrington Place	Y
LYNCH, Susanne	NHS Cheshire and Merseyside, Sefton Place	N
McKERRELL, Geraldine	Mersey Care NHS FT, Community Services Division	N
McNULTY, Sid Dr	St Helens and Knowsley Teaching Hospitals NHS Trust	Υ
MOONEY, Paul	Warrington and Halton Hospitals NHS Foundation Trust	N
PARKER, James	Warrington and Halton Hospitals NHS Foundation Trust	N
PATEL, Sejal	NHS Cheshire and Merseyside, Sefton Place	Y
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	Y
THORNTON, Dave	Liverpool University Hospitals NHS Foundation Trust (Aintree)	Y
VAN MIERT, Matthew Dr	Wirral University Teaching Hospital NHS Foundation Trust	N
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
ZAMAN, Asif	NHS Cheshire and Merseyside, Wirral Place	Y
Non-voting members		
BARNETT, Rob Dr	Liverpool Local Medical Committee	N
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	Y
In attendance		
DINGLE, Helen	Midlands and Lancashire Commissioning Support Unit	Υ
DONLON, Kieron	Midlands and Lancashire Commissioning Support Unit	N
MARSDEN, Ashley	North West Medicines Information Centre	Υ
MORONEY, Tamsin	Midlands and Lancashire Commissioning Support Unit	Υ
READER, Graham	Midlands and Lancashire Commissioning Support Unit	Y

1 Welcome and apologies

The Chair welcomed members. The Chair also welcomed new member Asif Zaman, Lead Pharmacist for NHS Cheshire and Merseyside, Wirral Place.

Apologies were accepted from Dr Adit Jain, Nick Cross, Dr Rob Barnett, Susanne Lynch (Sejal Patel attending), Geraldine McKerrell, Mo Azar, Dr David Reade, Kieron Donlon.

2 Declarations of interest and quoracy

There was one declaration of interest for item 5.6 from Sejal Patel, whose close relative works for Astra Zeneca. No further action was required for this indirect interest.

A quoracy check confirmed that this meeting was not quorate, from a primary care perspective.

3 Minutes of the last meeting

The Minutes of the APC meeting on 22 June 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.

4 Matters arising

There were no matters arising.

5 New Medicines

5.1 Faricimab for diabetic macular oedema (TA799)

NICE TA799 is a Fast Track TA, published on 29 June 2022. Faricimab is recommended as an option for treating visual impairment due to diabetic macular oedema in adults, only if certain criteria are met. Faricimab must be provided according to the commercial arrangement, which is a patient access scheme (PAS) discount.

This is a tariff-excluded high cost drug and is for specialist use only, therefore a red statement has been produced. Costs are based on the NICE Resource Impact Template, using the NHS list price, and include any additional administration costs. The resource impact will be less once the PAS discount is applied. Local costings will be detailed on the APC report.

There were no questions, and the APC approved the red statement.

5.2 Faricimab for wet age-related macular degeneration (TA800)

NICE TA800 is a Fast Track TA, published on 29 June 2022. Faricimab is recommended as an option for treating wet age-related macular degeneration in adults, only if certain criteria are met. Faricimab must be provided according to the commercial arrangement, which is a PAS discount.

This is a tariff-excluded high cost drug and is for specialist use only, therefore a red statement has been produced. Costs are based on the NICE Resource Impact Report. Local costings will be detailed on the APC report.

There were no questions, and the APC approved the red statement.

5.3 Risankizumab for psoriatic arthritis (TA803)

NICE TA803 is a Fast Track TA, published on 13 July 2022. Risankizumab is recommended, alone or with methotrexate, as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them, only if certain criteria are met. Risankizumab must be provided according to the commercial arrangement, which is a PAS discount.

This is a tariff-excluded high cost drug and is for specialist use only, therefore a red statement has been produced. NICE does not expect implementing this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £9,000 per 100,000 population. This is because risankizumab is a further treatment option and is available at a similar price to the current treatment options. Local costings will be detailed on the APC report where available.

There were no questions, and the APC approved the red statement.

5.4 Romosozumab for osteoporosis (TA791)

NICE TA791 was published on 25 May 2022 and recommends romosozumab as an option for treating severe osteoporosis in people after menopause who are at high risk of fracture, only if certain criteria are met. Romosozumab must be provided according to the commercial arrangement, which is a PAS discount.

This is a tariff-excluded high cost drug and is for specialist use only, therefore a red statement has been produced. Costs are based on the NICE Resource Impact Template, using the NHS list price, and include any additional administration costs as well as additional drug costs. The resource impact will be less once the PAS discount is applied. Local costings will be detailed on the APC report.

A discussion was had about the wording used by NICE, namely, "people after menopause"; and it was queried whether this would also apply to people who have gone through 'male menopause'. It was agreed that the correct terminology used for males is andropause, not menopause, and that the TA would not extend to use in these patients. The wording used in the TA applies to people who have been through the menopause but who may not identify as female.

There were no further questions, and the APC approved this red statement.

5.5 Patiromer for hyperkalaemia (TA623) - Review of red and amber initiated statements

This is a routine review of an existing red statement and amber initiated statement at expiry, both proposed for inclusion on the static list. There is no new evidence and no significant changes have been made to the documents. Costs have been revised following the update to the NICE Resource Impact Template for patiromer and sodium zirconium in January 2022.

Consultation was undertaken prior to formation of the ICS. Consultation feedback from one CCG requested that the amber initiated statement should include more direction around monitoring and how to contact the specialist team for support. NMSG felt it was

not necessary to include contact details for all specialist teams on the statement as contact details should be included in communications from the specialist when primary care prescribing is requested. This was clarified on the statement. Monitoring requirements were already addressed on the statement under 'Local implementation recommendations' which states that initial titration and monitoring should be done by the specialist during titration and ongoing monitoring is not expected to be different to current practice for patients with heart failure or stages 3b to 5 chronic kidney disease.

Clarification has been added regarding action to take if changes are required to medicines that may affect serum potassium. Prescribing information has been updated to include the instructions on how to make up the patiromer dose from the SPC.

It was queried whether the amber initiated statement should also specify that acid-base abnormalities should be corrected in hyperkalaemia. MV advised that while sodium bicarbonate is still used for treatment of acidosis in CKD, it is no longer recommended for use in hyperkalaemia alone.

Both statements already have existing CCG approvals and TM asked how these should be dealt with. The Chair proposed that Places should carry existing CCG approvals over as before, until the APC hears anything different from the ICB; there were no objections to this.

The APC approved both statements for inclusion on the static list, and to carry forward existing approvals.

5.6 SGLT2 inhibitors in heart failure - Review of supporting documents to include empagliflozin

The existing pathway and GP letter have been updated to include empagliflozin, following publication of NICE TA773. NMSG agreed that the specialist should stipulate which SGLT2 inhibitor should be initiated, and the GP letter has been updated to reflect this.

Consultation was undertaken prior to formation of the ICS. Minor amendments have been made to the pathway to clarify monitoring requirements following consultation feedback from one CCG, and two CCGs requested that the GP letter should include a named clinician instead of 'Heart Failure team.' The GP letter has been updated to include specialist name and role, specialist contact details and name of responsible consultant (if applicable).

NMSG propose that the SGLT2 inhibitor patient information leaflet is withdrawn and replaced by the manufacturer's patient information leaflets for dapagliflozin and empagliflozin. Links to these have been included in the GP letter.

It was noted by NMSG that AstraZeneca withdrew the DKA patient alert card and risk minimisation materials for dapagliflozin when the license for type 1 diabetes was withdrawn. There are no risk materials and there is no requirement to issue a DKA alert card from the manufacturer for empagliflozin and NMSG therefore propose that the DKA alert card for SGLT2 inhibitors in heart failure is withdrawn. Consultation feedback from one CCG was supportive of withdrawing the DKA alert card, no other comments were received regarding this.

A discussion was had regarding the proposal to withdraw the DKA alert card. It was noted that there have been implementation issues with the card and clinicians have reported difficulties in printing out the card. One member asked why the alert card is being

withdrawn as there is still a risk of DKA in type 2 diabetes. Another member asked if anything has changed clinically to justify removing the alert card and queried whether it was a matter of cost and administration rather than a clinical reason.

TM advised that the requirement for a DKA alert card was based on the manufacturer's initial requirement for dapagliflozin and applied only for use in type 1 diabetes. There are existing APC statements for use of SGLT2 inhibitors in type 2 diabetes and a DKA alert card was not produced or deemed necessary for these. MV reiterated this and advised that there would be no requirement to have a DKA alert card for use of SGLT2 inhibitors in heart failure alone, but there is still a requirement for the clinician to counsel the patient regarding DKA risk.

The APC agreed to withdraw the DKA alert card and approved the supporting documents. It was also agreed to withdraw the SGLT2 patient information leaflet and replace this with the manufacturers' patient information leaflets.

6 Formulary and Guidelines

6.1 Asthma guidelines

This is a review of the current adult asthma guideline that incorporates the work of the Cheshire and Merseyside low carbon inhalers steering group. Taking fuller account of inhaler carbon footprint and recent new products are the major reasons for this review and it supports first choice inhaler options across the pathway and the national and global agenda of climate change and a greener NHS.

The guidance offers a pathway for both dry powder inhalers (DPI) and metered dose inhalers (pMDI) with a greater number of preferred options to support with patient clinical need and/or preference, with emphasis on the 'greener' DPI pathway from a carbon footprint perspective.

The document has been considered from both a Pan Mersey and Cheshire footprint to ensure sustainability across the whole of the Cheshire and Merseyside region with an aim to reduce variation. Feedback was constructive and has been fully addressed.

In addition, the subgroup would like to propose withdrawing the current tiotropium in adult asthma statement as this is now covered by the updated guideline and is established practice.

The APC approved the adoption of the new adult asthma guideline, and for existing approvals to be carried forward. The committee also confirmed its support for the removal of the tiotropium statement.

6.2 North West Coast Clinical Network Palliative Care guidelines

The North West Coast Clinical Network Palliative Care guidelines were adopted by Pan Mersey APC in 2018 with a link to the guidelines added to the formulary. The guidelines were subsequently adopted by Lancashire and South Cumbria Medicines Management Group. They were due to be reviewed but this was significantly delayed due to the Covid pandemic. Lancashire and South Cumbria have subsequently undertaken a review and updated the guidelines. The End of Life Care Network have reviewed, and support, the updated guideline and propose it should be adopted in Cheshire and Merseyside as well.

FGSG hosted the guideline through the Pan Mersey APC consultation process. Stakeholder feedback was noted but the Network felt comments received did not warrant any changes to the guidelines. The FGSG accepted this position as this guideline sits alongside any locally developed guidelines with any minor differences being clinically insignificant.

The APC agreed to the adoption of the NW Coast Clinical Network Palliative Care guideline with an updated link being added to the Pan Mersey formulary once it has been added to the NW Coast Clinical Network website.

6.3 **DOAC** project decision aid documents

The Cheshire & Merseyside Health and Care Partnership (C&M HCP) has developed documents to assist in initiating and reviewing patients prescribed DOACs for AF and promoting use of edoxaban as first-choice DOAC in AF. They include a decision aid for initiating a DOAC in AF, a decision aid for medicines optimisation review of patients prescribed apixaban, and frequently asked questions. The documents have been shared with Pan Mersey APC stakeholders for further comments with a view to being adopted by Pan Mersey APC once they have been through its process.

The consultation feedback raised a few queries regarding the use of edoxaban in obese patients, administration via a feeding tube, and using the term 'preferred DOAC' and these have been addressed.

National guidance has just been published on 22 July and this is compatible with the C&M HCP documents apart from two points. Firstly, in the national guidance with regard to patients over 120kg it is stated edoxaban is less suitable and, secondly, edoxaban should be used with caution if creatinine clearance exceeds 95ml/min. However, the view from the C&M HCP expert clinicians is that edoxaban is still suitable in these circumstances and they submitted evidence to the national process to support this position.

It was proposed that the APC adopts the C&M HCP documents as the DOAC project is a local and national priority. Further discussion will take place regarding the two differences from the national guidance. Should there be any relevant changes following reconsideration of these points then these will be brought back to the APC. In the meantime, the documents were approved for APC adoption in their current form.

6.4 Trimbow NEXThaler dry powder inhaler for COPD

It was proposed to add Trimbow NEXThaler dry powder inhaler (DPI) (beclomethasone 88mcg/formoterol 5mcg/glycopyrronium 9mcg) to section 3.2 of the formulary for Chronic Obstructive Pulmonary Disease (COPD) indication in adults, with a green RAG designation.

Trimbow NEXThaler (DPI) joins Trelegy Ellipta (DPI) and Trimbow metered dose inhaler (MDI) as a single inhaler triple therapy option licensed for maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting $\beta 2$ agonist or a combination of a long-acting $\beta 2$ agonist and a long acting muscarinic antagonist.

The dose is two inhalations twice daily. Trimbow NEXThaler is the same price as the other two triple inhalers on the formulary for the treatment of COPD and has a low carbon footprint.

The consultation feedback received was in agreement and no issues were raised. The APC approved this formulary addition.

6.5 Otigo ear drops

The Formulary and Guidelines subgroup proposed the addition of Otigo® ear drops (phenazone 40mg and lidocaine hydrochloride 10mg) to the formulary, with a green RAG designation, for the treatment of acute otitis media.

In March 2022, NICE updated NG91 - Otitis Media (acute): antimicrobial prescribing to add a recommendation on ear drops containing an anaesthetic and an analgesic because a licensed preparation (Otigo®) is now available in the UK. Otigo® is licensed for local symptomatic treatment and relief of pain in the following diseases of the middle ear without tympanic perforation:

- · acute, congestive otitis media;
- otitis in influenza, the so called viral bullous otitis;
- barotraumatic otitis.

The cost is £8.92 for 15ml. The antimicrobial subgroup is in the process of adding it to the antimicrobial guidelines.

Consultation feedback was in agreement. The APC raised no questions and approved the addition of Otigo to the formulary.

6.6 **Biologics dose escalation**

The subgroup proposed the addition of dose escalation guidance to the Pan Mersey Inflammatory Bowel Disease High-Cost Drugs Treatment Pathway for Adults, to reflect current practice for patients with Crohn's disease. Some trusts were submitting individual funding requests which led to a cohort of patients being identified. On further investigation, it was identified that dose-escalation is established clinical practice in all local trusts that treat these patients, following discussion and agreement within multidisciplinary teams. There is evidence to support dose-escalation as an alternative to switching to another drug and this is listed in the pathway.

The consultation feedback was in support but there was a query about why this was only for patients with Crohn's disease. The subgroup has agreed to add ulcerative colitis to the work plan. There was concern about a potential increase in cost, but it is expected that there are unlikely to be additional costs as this is already current practice.

The red statement for the use of filgotinib for patients with moderately to actively severe ulcerative colitis, in line with NICE TA 792 was agreed at the June APC meeting. This has also been added to the pathway.

There were no questions, so the APC approved the addition of dose escalation guidance for Crohn's disease, and filgotinib for ulcerative colitis, to be added to the Inflammatory Bowel Disease High-Cost Drugs Treatment Pathway, and for the existing approvals to be carried forward.

7 Shared Care

7.1 Dapsone Shared care framework

This is a routine review of the dapsone shared care framework at the review by date. The maximum dose has been reduced to 200mg daily in line with British Association of Dermatology guidance and the pregnancy and breastfeeding guidance has been updated, including removing a reference to prescribing in patients with leprosy because this indication is not covered by this framework. Other minor changes have also been made.

The consultation feedback raised a few queries. There was concern about the unfamiliarity of prescribing such a rare drug. Prescribing data for Pan Mersey indicate that prescribing is higher in some areas than in others and the concern from this Place was understandable as just one dapsone prescription was dispensed in the last 12 months. There was a query about dosing which has been addressed and one Place reported implementation issues.

No issues or questions were raised by the committee members. The APC approved this reviewed framework and for approvals to be carried forward.

7.2 Methadone statement and prescribing support information

This is a routine review of the methadone statement, prescribing support information and GP letter at the review by date. When these documents were first discussed by the shared care subgroup, concerns were raised by some of the primary care representatives. These were discussed with Devina Halsall, the NHSE/I accountable officer for controlled drugs and, following that, several significant changes have been made. It is stressed that a full individualised plan should been made with each patient, that patients who wish to reduce their dose should be fully supported, and it has been made clearer that opioid rotation and cross titration should only be done by the specialist.

The consultation feedback was constructive, and it has all been addressed. It is noted that methadone remains red for much of Pan Mersey, but the subgroup hopes that these changes will make the documents easier to use.

The APC approved these documents and for the existing approvals to be carried forward.

8 APC reports

8.1 NICE TA Adherence Checklist (June 2022) – for noting

Pan Mersey APC is compliant up to the end of June 2022. The report will be uploaded to the APC website.

8.2 APC Annual Report 2021/22 – for noting

AH presented the APC Annual Report, for noting. This will be published on the APC website.

9 APC and the ICS

9.1 Update

NHS Cheshire and Merseyside became the statutory organisation on 1 July 2022. Until told otherwise, the committee has been asked to continue business as usual. It is currently unclear as to how the APC decisions made today will be ratified. AH has made contact with the Cheshire and Merseyside Medicines Optimisation Steering Group for advice as they may have some routes into the ICB that they can utilise. The APC Report that is sent out the day after the APC meeting, which details the recommendations, will be sent out as usual tomorrow but will acknowledge the move to ICB. If Place colleagues can escalate via their internal routes as well, it would be helpful.

A banner has been added to the top of all pages on the APC website containing a statement that all existing CCG commissioning policies remain in place until such time as the ICB has undertaken a full review and issued a suite of single commissioning policies. This is based on the statement on the ICB website, with a link to the full statement.

9.2 **C&M APC Engagement Report – for noting**

The two engagement events went ahead as planned, and a post-event survey was sent to the attendees. Attendees were in agreement that the best approach moving forward is a single new APC across Cheshire and Mersey. A report of the findings has been circulated to stakeholders and an accompanying draft board report prepared. The next steps are for the MIAA Medicines Optimisation Steering Group to lead on taking this to the ICB, who will then make a decision and confirm the outcome and next steps. The APC will be informed when any decision has been made.

10 Any other business

10.1 Abrocitinib for dermatitis (Early Access to Medicines Scheme) – part of NICE MTA

There is a NICE MTA for abrocitinib, tralokinumab and upadacitinib for dermatitis that is due for publication on 3 August 2022. Abrocitinib is part of the Early Access to Medicines Scheme (EAMS) and there is a 30-day implementation period for NICE TAs for EAMS drugs. The committee was advised that the implementation deadline will not be met because there is no APC meeting in August.

The APC noted this.

11 Next meeting

THERE IS NO APC MEETING IN AUGUST

Next meeting will be on Wednesday 28 September 2022 at 2.00 - 4.00 pm. Online meeting via Microsoft Teams.