



Minutes

Meeting	Pan Mersey Area Prescribing Committee
Venue	Microsoft Teams online meeting
Date and time	Wednesday 28 September 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	Y
BARK-JONES, Jo	Bridgewater Community Healthcare NHS Foundation Trust	Y
BARTON, Carolyn	NHS Cheshire and Merseyside, Knowsley Place	N
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	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
DOYLE, Catherine Dr	NHS Cheshire and Merseyside, Warrington Place	Y
FITZGERALD, Richard Dr	Liverpool University Hospitals NHS Foundation Trust	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 Cheshire and Merseyside, Sefton Place	Y
JAIN, Adit Dr	NHS Cheshire and Merseyside, Knowsley Place	N
JOHNSTON, Jennifer	NHS Cheshire and Merseyside, Sefton Place	Y
JOHNSTONE, Peter (Chair)	NHS Cheshire and Merseyside, Liverpool Place	Y
JOSEPH, Smitha Dr	NHS Cheshire and Merseyside, Halton Place	Y
KNIGHT, Lisa	Wirral Community Health and Care NHS Foundation Trust	N

Members	Organisation	Present
LLOYD, Barry	NHS Lancashire and South Cumbria, West Lancashire Place	Υ
LOI, Annie	NHS Cheshire and Merseyside, Knowsley Place	Y
LUNN, Jenny	NHS Cheshire and Merseyside, Warrington Place	
LYNCH, Susanne	NHS Cheshire and Merseyside, Sefton Place	
McKERRELL, Geraldine	Mersey Care NHS FT, Community Services Division	N
McNULTY, Sid Dr	St Helens and Knowsley Teaching Hospitals NHS Trust	
MOONEY, Paul	Warrington and Halton Hospitals NHS Foundation Trust	Y
PARKER, James	Warrington and Halton Hospitals NHS Foundation Trust	
SANDERSON, Paul	Alder Hey Children's NHS Foundation Trust	N
SKIPPER, Paul	Liverpool University Hospitals NHS Foundation Trust (Royal)	N
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	N
WELSBY, Mike	St Helens and Knowsley Teaching Hospitals NHS Trust	Y
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	Υ
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		
MARSDEN, Ashley	North West Medicines Information Centre	Υ
MORONEY, Tamsin	Midlands and Lancashire Commissioning Support Unit	Y
READER, Graham	Midlands and Lancashire Commissioning Support Unit	Υ
WILSON, Paula	Midlands and Lancashire Commissioning Support Unit	Υ

1 Welcome and apologies The Chair welcomed members. The Chair also welcomed new member Dr Smitha Joseph who will be temporarily covering the Halton Prescribing Lead role on the committee.

Apologies were accepted from Susanne Lynch (Jenny Johnston attending), Dr Adit Jain (Peter Johnstone, Acting Chair), Dr Rob Barnett, Carrie Barton (Annie Loi attending),

Jimmy Cheung (Jo Bark-Jones attending), Geraldine McKerrell, Paul Sanderson, and Helen Dingle.

2 Declarations of interest and quoracy

There was one declaration of interest for items on the agenda from AI, for item 9.1.

A quoracy check confirmed that this meeting was quorate.

3 Minutes of the last meeting

The Minutes of the APC meeting of 22 June 2022 and the APC meeting of 27 July 2022, were agreed to be accurate records of the meetings and were formally ratified.

4 Matters arising

<u>DOAC</u> project decision aid documents: In discussions in July, the APC agreed to support these DOAC documents, but the national guidance was published just before the APC meeting, and committee members felt it was necessary to get confirmation that due consideration has been given to the national guidance. There are slight differences between local and national guidance and the Cardiac Board has confirmed that they support local guidance, despite it being at a slight variance to national guidance, in the following areas:

- 1. Locally, edoxaban can be used in obese patients
- 2. Locally, edoxaban can be used in patients who have a creatinine clearance greater than 95 mls/min
- 3. Locally, actual body weight is recommended for calculating creatinine clearance, as per clinical trial evidence.

This was approved at the Cardiac Board meeting last week.

The APC was asked if it agrees that we have now discharged our responsibility around those differences. The APC agreed. The hyperlinks to the documents will now be added to the formulary, as agreed in July, and will also be added to the Pan Mersey DOACs in AF statement.

5 New Medicines

5.1 **Grey statement summary**

The following grey 'holding' statements have been produced for the APC website:

EMPAGLIFLOZIN film-coated tablets (Jardiance®) Chronic heart failure with preserved or mildly reduced ejection fraction: To be reviewed when the NICE TA is published (currently TBC).

TRIFAROTENE cream (Aklief® ▼) Cutaneous treatment of acne vulgaris: To be reviewed if an application for use is received and prioritised.

SOMATROGON injection (Ngenla® ▼) Growth disturbance in children and young people: To be reviewed when the NICE TA is published (currently TBC).

<u>UPADACITINIB tablets (Rinvoq®▼) Moderately to severely active ulcerative colitis</u>: To be reviewed when the NICE TA is published (expected 04 January 2023).

The APC noted the grey statements produced and the proposed timescales for review.

5.2 Abrocitinib, tralokinumab or upadacitinib for atopic dermatitis (NICE TA814 - EAMS)

NICE TA814 was published on 03 August 2022 and recommends abrocitinib, tralokinumab and upadacitinib as options for treating moderate to severe atopic dermatitis that is suitable for systemic treatment in adults, only if certain criteria are met.

TA814 also includes criteria for abrocitinib and upadacitinib for treatment of young people aged 12 years and over, however treatment in adolescents is commissioned by NHS England.

It was noted at July APC that abrocitinib was made available through 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 would not be met because there is no APC meeting in August.

These are tariff-excluded high cost drugs and are 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. The resource impact will be less once the PAS discount is applied.

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

Post meeting note:

Following APC, costs have been re-calculated using the NICE resource impact template and have been updated on the statement.

5.3 Brolucizumab for diabetic macular oedema (NICE TA820 - Fast Track)

NICE TA820 is a Fast Track TA and was published on 31 August 2022. The 30-day implementation deadline for Fast Track TAs will be achieved. Brolucizumab is recommended as an option for treating visual impairment due to diabetic macular oedema in adults, only if certain criteria are met.

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 because brolucizumab is a further treatment option and is available at a similar price to the current treatment options.

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

5.4 Guselkumab for active psoriatic arthritis (NICE TA815)

NICE TA815 was published on 31 August 2022 and updates and replaces NICE TA711.

Guselkumab is recommended 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. The updated recommendations allow for all people who have previously received a biological treatment and people who have contraindications to a TNF-alpha inhibitor to access guselkumab.

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 because guselkumab is a further treatment option and is available at a similar price to the current treatment options.

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

5.5 | Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events (NICE TA805)

NICE TA805 was published on 13 July 2022 and recommends icosapent ethyl as an option for reducing the risk of cardiovascular (CV) events in adults if they have a high risk of CV events, raised fasting triglycerides (1.7 mmol/litre or above) and are taking statins.

Icosapent ethyl must only be used for secondary prevention of CV events and is not recommended for primary prevention. Patients must have established CV disease and LDL-cholesterol levels above 1.04 mmol/litre and below or equal to 2.60 mmol/litre.

Icosapent ethyl can be initiated in both primary and secondary care and NICE expects that the majority of prescribing will take place in primary care, therefore a green statement has been produced. Costs are based on the NICE resource impact report.

TM gave a summary of the statement and went through each section. It was noted that the trial information in the effectiveness section was taken directly from the NICE TA. SMc suggested that the document would be more useful if it included further details from the REDUCE-IT trial as it is helpful to refer to number needed to treat (NNT) and absolute risk reduction of events when counselling patients. It was agreed to add the details regarding NNT and absolute risk reduction from the trial.

TM

The APC approved the green statement with the proposed amendments. It was agreed that the amendments to the statement would not need to be brought back to the next APC meeting as it is a minor addition which supports, but does not change, the message.

5.6 Roxadustat for anaemia in chronic kidney disease (NICE TA807)

NICE TA807 was published on 13 July 2022 and recommends roxadustat as an option for treating symptomatic anaemia associated with chronic kidney disease (CKD) in adults, only if certain criteria are met.

This 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.

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

5.7 Oral bisphosphonates for osteoporosis

This is a routine review of the existing green statement at expiry. TM gave a summary of the statement and went through the updates to each section.

The statement has been updated following re-consultation in July and includes the most recent NOGG guidance (September 2021). Recommendations regarding treatment duration have been amended in line with NOGG guidance and the flowchart for long term treatment and monitoring has been added, which addresses feedback from previous consultation requesting clarity on this. Safety information has also been updated to include the SDCEP guidance for management of patients at risk of medication-related osteonecrosis of the jaw.

NMSG were able to accommodate some of the consultation feedback but agreed that some comments would be outside the scope of the current green TA statement. However,

it will be raised with FGSG to consider whether development of a guideline is required instead.

The statement will be kept live and not added to the static list. The APC approved the updates to this green statement and Places confirmed that existing approvals can be carried over.

5.8 Non-renewal of NMSG statements (March 2022 – March 2023)

The NMSG considers that the NICE TA recommendations for the following drugs are now established into clinical practice and the associated policy statements do not add any further additional benefit. The NMSG proposed that the statements are archived at expiry (or immediately if already expired) and the links to the NICE TAs will be retained in the relevant formulary entries.

- 1. AVATROMBOPAG tablets (Doptelet® ▼) for treating severe thrombocytopenia in adults with chronic liver disease having planned invasive procedures
- 2. BARICITINIB film-coated tablets (Olumiant®▼) for atopic dermatitis
- 3. BROLUCIZUMAB solution for injection (Beovu®▼) for treating wet age-related macular degeneration
- 4. FILGOTINIB tablets (Jyseleca® ▼) for moderate to severe rheumatoid arthritis
- 5. GALCANEZUMAB injection (Emgality®▼) for prevention of migraine
- 6. LIRAGLUTIDE injection (Saxenda®) for managing overweight and obesity
- 7. UPADACITINIB prolonged-release tablets(RINVOQ®▼) for treating severe rheumatoid arthritis
- 8. USTEKINUMAB solution for injection (Stelara®) for ulcerative colitis

<u>Grey statements</u>: The NMSG proposed that where a Grey statement is issued and no expression of interest is received within 2 years then the Grey statement will be archived, and the drug remain as Grey in the formulary. The following two statements fall into this category:

- 1. DIENOGEST tablets (Zalkya® ▼) for endometriosis
- 2. PRIDINOL tablets (Myopridin®) for central and peripheral muscle spasms

The APC confirmed their approval to the above proposals.

6 Formulary and Guidelines

6.1 Actimorph (morphine sulphate orodispersible tablets) addition to formulary

The subgroup proposed the addition of morphine sulphate orodispersible tablets (Actimorph®) to the Pan Mersey Formulary, for use in accordance with the product's marketing authorisation and as a second-line option after oral morphine solution (RAG green).

The application for use has come from palliative care. GR went through the details of the proposal and then the feedback received in the consultation process. Actimorph® is licensed for severe pain which can be adequately managed only with opioids. The following strengths are marketed in the UK: 1mg, 2.5mg, 5mg, 10mg, 20mg, 30mg (Schedule 2 Controlled Drugs).

Oral morphine solution will remain the first-choice product, but Actimorph® will be considered on an individual basis. It is difficult to determine how many patients will be prescribed Actimorph® since the decision to prescribe it will be based on whether it is appropriate for the individual patient.

Potential benefits of having Actimorph® available as an option:

- Easier to monitor patient compliance and identify exactly what dose of 'as required' morphine the patient has been using. This facilitates safe decision-making about changes to treatment.
- 2. Ease of administration (e.g., less time taken to administer a tablet versus liquid for staff (although note Schedule CD); easier for the patient to take a tablet, rather than measure the liquid)
- 3. Travel (e.g., day trips, air travel)
- 4. Some patients find oral morphine solution may sting or taste unpleasant. It is a little more expensive than oral morphine solution but less expensive than the standard morphine tablets.

In response to the secondary care feedback regarding confusion between preparations and the risk of administration error, SMc asked if there was a way to mitigate the risk. The subgroup felt this was down to individual organisations. There was discussion on (a) the requirement for the APC to advise further, (b) confusion with multiple different versions of morphine with different names, and (c) inadvertent co-prescribing with other opiates. The subgroup felt that any risk is also applicable to the standard tablets which are already on the formulary. However, it was felt this issue is not new, and the dangers are known so it was agreed that the information that will be added to the formulary is appropriate for the purpose of this committee. It was noted there is a potential for reduced dosing errors in primary care compared to oral liquid.

Some Trusts will place restrictions on how it is used internally, e.g. palliative care. SMc confirmed that St Helens and Knowsley Trust does have risk mitigation systems. Safety systems are in place in Warrington Place, and it was pointed out that there are already multiple formulations of opiates which carry risks.

The APC approved the addition of Actimorph to the formulary as proposed.

6.2 Omeprazole oral liquid RAG change

There is significant use of omeprazole oral liquid across Pan Mersey, costing nearly £900,000 annually. The cost of using orodispersible tablets instead would be significantly less (£32,000). The subgroup proposed a change of RAG designation for omeprazole oral liquid from Green (Amber Recommended in children < 12 years of age) to Black (Amber Recommended in children <2kg or <1 year old with a narrow feeding tube, and Green in other patients with a feeding tube at risk of tube blockage). The FGSG has liaised with Alder Hey regarding this.

Omeprazole oral liquid should be used only where dispersible tablets cannot be. Any child >2kg can be started with 5mg daily administered as half a 10mg dispersible tablet (unless they have a feeding tube at risk of blockage).

The APC approved this RAG change.

6.3 Ankylosing spondylitis and non-radiographic axial spondyloarthritis statement and pathway - updated

The existing statements and pathway have been updated to include NICE TA's 718 and 719 for secukizumab and ixekizumab (already approved by APC). This has been updated in consultation with the Mersey Rheumatology Group.

The APC approved these updated documents, and to the carry-over of previous CCG approvals.

6.4 Adult-onset Stills disease statement and pathway – updated

The existing statement and pathway have been updated to include NICE TA685 for anakinra, and a link to the NHSE commissioning policy, stating that it commissions tocilizumab for adult-onset Still's disease. This has been updated in consultation with the Mersey Rheumatology Group.

The APC approved these updated documents, and to the carry-over of previous CCG approvals.

6.5 **Headache pathway**

The Walton Centre has updated the pathway. They have included the following amendments:

PAGE TWO AMENDMENTS:

- 1. MIGRAINE SECTION rewording to specify other commonly associated features
- 2. MEDICATION OVER USE SECTION Specifying that the doses given within the MEDICATION OVERUSE section is what is classed as "overuse"
- 3. CLUSTER HEADACHE SECTION amended from "rarely up to 2 hours" to "rarely up to 4 hours" and further clarification of "ipsilateral autonomic features"
- 4. OTHERS SECTION added in triggers for TGN, added in "commonly associated with migraine" for ice pick

PAGE THREE AMENDMENTS:

- 1. Specific guidance regarding reducing analgesia previously document said "reduce excessive analgesia use"
- 2. Topiramate dosing updated
- 3. Amitriptyline section updated to state "avoid if poor quality sleep or restless legs syndrome"
- 4. Valproate section updated to a blanket statement "valproate medicines must not be used in women of childbearing potential"
- 5. Topiramate section updated to match MHRA July 2022 safety update and added in that a pregnancy test should be performed before initiation of treatment.

The APC approved the updated pathway, and to the carry-over of previous CCG approvals.

6.6 FGSG document expiry extensions and document withdrawals

The FGSG proposed that the following documents that will pass their review-by date in the near future could be considered for an extension to their review-by date until Oct/Dec 2023, as major changes are thought to be unlikely. This would be reviewed on a case-by-case basis should significant developments occur:

Document	Review-by	Proposal
Botulinum Toxin Type A injection for severe axillary hyperhidrosis	October 2022	October 2023
Botulinum Toxin Type A for chronic anal fissure	October 2022	October 2023
Formulary Chapter 10	October 2022	October 2023

BRONCHIECTASIS (non-cystic fibrosis), nebulised antibiotics	November 2022	October 2023
Dry eye symptoms, non-specialist management	January 2023	Dec 2023
Formulary Chapter 6	January 2023	Dec 2023
Formulary Chapter 11	January 2023	Dec 2023
Elasticated Viscose Stockinette ('Viscose') Garments	February 2023	December 2023

The FGSG recommends the following statements are withdrawn:

Statement	Notes	
ACETYLCYSTEINE in idiopathic pulmonary fibrosis	Established practice. Will remain Black-designated entry in formulary	
ALISKIREN tablets (Rasilez®) for Hypertension	Established practice. Will remain Black-designated entry in formulary	
GLIPTINS (Dipeptidylpeptidase-4 [DPP-4] inhibitors)	Established practice.	
TRIMIPRAMINE capsules and tablets (Surmontil®)	Established practice. Will remain Black-designated entry in formulary	
MINOCYCLINE for acne	Established practice. Will remain Black-designated entry in formulary	

The APC confirmed their approval of the proposals.

7 Shared Care

7.1 Hydroxychloroquine prescribing support information – minor update

In July 2022, the Regional Medicines Optimisation Committee (RMOC) published practical recommendations for safe ophthalmology monitoring for patients who are receiving long term hydroxychloroquine and chloroquine. This is based on updated guidance from the Royal College of Ophthalmology (RCOphth), published in 2020.

The prescribing support information had already been updated to reflect the RCOphth guidance which was approved by APC in May 2021. For completeness, the RMOC guidance has been added to the references.

APC committee members approved this minor update and for existing approvals to be carried over.

8 APC reports

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

Pan Mersey APC is compliant up to the end of August 2022, with the exception of not meeting the 30-day EAMS deadline for TA814.

A query was raised regarding the 30-day implementation period for EAMS and Fast Track TAs. AH clarified that although EAMS and Fast Track TAs have a 30-day implementation period, the APC stance has always been that the 90-day implementation period is the statutory requirement, and this has not changed.

The report will be uploaded to the APC website.

8.2 **RMOC update**

AH provided an update.

The RMOC NHSE shared care frameworks have all been signed off and published now. The Shared Care Subgroup looked at the RMOC draft documents and compared them with the APC documents when they were circulated for national consultation. There have been further changes to the RMOC documents as a result of consultation feedback, it is therefore necessary for the SCSG to compare the documents again and make a proposal whether to adopt the RMOC documents in their entirety or retain the existing Pan Mersey documents. It will be necessary to go through a robust process, with any differences reconsidered and discussed fully by the shared care subgroup, and a report of recommendations will be brought to the APC in due course.

<u>RMOC Northwest</u>: The inaugural meeting was rescheduled to take place tomorrow but discussions at ICB and NHSE level have decided the best course of action is to postpone until the new financial year. AH will provide a further update when she has more information.

9 APC and the ICS (STANDING ITEM)

9.1 **Update**

<u>APC approvals</u>: an interim process has been agreed whereby APC recommendations are to be taken to the ICB Executive Team meeting for approval. There is now a template for producing a report to be sent after each APC meeting to the ICB for consideration. Some June and July APC recommendations have been ratified now. However, the ICB will not ratify individual decisions for Cheshire and Pan Mersey, they need to be the same in both areas, which will limit what can be brought to APC over the coming months and some items in process will have to be paused temporarily. The CSU team is currently working out how to collaborate with Cheshire in the interim, and AH is liaising with Cheshire APG.

There was a discussion at the Place Leads' meeting in September, prioritising what are the important things that need to go to ICB; it was decided that any operational documents that support implementation, or minor RAG changes, will be sent for noting rather than for ratification. The CSU has been asked to continue to send out the APC Report every month after the APC meeting, but it is "for information only, pending ICB approval". The same expression will be used on the APC website, to make it clear that items are pending approval.

A single Cheshire and Mersey APC has been approved in principle by the ICB. There are a couple of formulary chapter reviews which are due now and the intention is to pilot a

joint review with Cheshire to understand the process, differences, and what would need to be addressed. There will need to be a full harmonious programme to bring both APCs into alignment once the new APC is established.

<u>IBD Pathway</u>: an updated version of this pathway was brought to the APC meeting and following a discussion about dose escalation in the pathway, it was approved by the APC; however, the ICB will not consider a single Pan Mersey position as this creates inequity across Cheshire and Merseyside, but Cheshire do not support dose escalation so it cannot be taken to the ICB for ratification. It is therefore currently pending ICB approval on the website.

AH has two concerns, (1) clinicians might not realise that it is not approved by the ICB and work to the updated policy, and (2) it is a risk to the Pan Mersey APC reputation as it is at odds with the more recent ICB position of not having single APC recommendations. So, on that basis, it is proposed that, in the short term, the updated version is removed from the website, and we revert to the previous version that was approved by Pan Mersey APC in May 2021. Nothing else had changed in the pathway except dose escalation.

AH was asked if the IFR process could be used to secure funding for treatment for these patients and advised members that the IFR route would only be successful if the patient was deemed to be clinically exceptional. MW reminded members that if there is a patient who doesn't meet the IFR criteria for clinical exceptionality but may be different enough from the standard patient cohort to be suitable for funding consideration, then there are historic processes already in place to be able to approach Place leads to discuss further and then escalate within the ICB if appropriate. It was agreed that AH will put a summary of the situation into the APC Report so that members have an explanation to answer enquiries from the relevant clinicians.

AΗ

All declared an interest, that he is a newly appointed member of the ICB Board. He assured attendees that this was not the view of the Board so it must be from the Executive Committee. He expressed concern about what happens if there was a clinical risk and indicated he would make further enquiries within the ICB.

Going forward, the subgroups will not be bringing anything new to the APC Meeting without a joint Cheshire and Merseyside position. This situation highlights the need to merge the APCs with urgency. It was agreed, by majority, to withdraw the updated IBD pathway from the website and reinstate the previous version.

10 Any other business

None.

11 Next meeting

Wednesday 26 October 2022 at 2.00 – 4.00 pm Online meeting via Microsoft Teams