



Pan Mersey Area Prescribing Committee

14:00 – 16:00 hours Wednesday 25 September 2019 The Education Centre, Kent Lodge, Broadgreen Hospital, Thomas Drive, Liverpool, L14 3LB

Minutes

Members in Attendance	Organisation(s)
Peter Johnstone (Chair)	Prescribing Commissioner, Liverpool CCG
Dr Rob Barnett	LMC Representative, Liverpool
Dr Ivan Camphor	LMC Representative, Mid-Mersey
Nicola Cartwright	Assistant Director Medicines Management, St Helens CCG
Neil Chilton	Medicine Management Clinical Services Manager, North West Boroughs Healthcare NHS Foundation Trust
Caroline Crouch	Senior Medicines Optimisation Pharmacist, Wirral CCG
Dr Catherine Doyle	GP / Prescribing Lead, Warrington CCG
Alison Evans	Lead Medicines Management Pharmacist, Wirral University Teaching Hospital NHS FT
Dr Richard Fitzgerald	CRF Director / Consultant Physician Clinical Pharmacology, Chair Drug & Therapeutics Committee, RLBUHT
Dr Claire Forde	CCG Governing Body Member / Prescribing Lead, Halton CCG
Danny Forrest	Chief Pharmacist, Liverpool Heart and Chest Hospital FT
Paul Gunson	Deputy Head of Medicines Management, Knowsley CCG
Anne Henshaw	Senior Medicines Commissioning Pharmacist, MLCSU
Dr Anna Hunter	GP Clinical Lead, South Sefton CCG / Southport & Formby CCG
(formerly Ferguson)	, , , , , , , , , , , , , , , , , , , ,
Jasmeen Islam	Deputy Chief Pharmacist, Cheshire and Wirral Partnership NHS FT
Jenny Johnston	Senior Pharmacist, South Sefton CCG / Southport & Formby CCG
Jenny Jones	Principal Pharmacist Medicines Management, Warrington & Halton Hospitals NHS FT
Barry Lloyd	Medicines Optimisation Pharmacist, West Lancashire CCG
Jenny Lunn	Pharmaceutical Adviser & Team Lead, Medicines Management, Warrington CCG
Dr Sid McNulty	Consultant Endocrinologist / Chair Drug & Therapeutics Committee, St Helens & Knowsley Teaching Hospitals NHS Trust
Dr Shankara Nagaraja	Consultant Intensivist/Anaesthetist, Associate Medical Director for Clinical Governance, University Hospital Aintree
James Parker	Lead Pharmacist Medicines Optimisation, RLBUHT
Kathryn Phillips	Medication Safety Officer, Bridgewater Community Healthcare NHS FT
Lucy Reid	Head of Medicines Management, Halton CCG
Dr Omar Shaikh	Clinical Lead GP for Medicines Management, St Helens CCG
Jackie Szynalski	Medicines Management Pharmacist, Mersey Care Community Services
Dave Thornton	Assistant Clinical Director of Pharmacy, University Hospital Aintree
Dr Matthew Van Miert	Consultant Anaesthetist, Wirral University Teaching Hospitals NHS FT
Mike Welsby	Pharmacist, St Helens & Knowsley Teaching Hospitals NHS Trust
John Williams	Chief Pharmacist, Southport and Ormskirk Hospital NHS Trust
Attendees	Organisation(s)
Emma Jaeger	Medicines Optimisation Pharmacist, Wirral CCG
Emma Kelly	Advanced Clinical Pharmacist, Acute Medicine, University Hospital Aintree
Graham Reader	Senior Medicines Commissioning Pharmacist, MLCSU
Paula Wilson	Head of Medicines Optimisation, MLCSU

APC/19/58	Welcome and apologies	Action
	The Chair welcomed members and welcomed an observer, Emma Kelly, Advanced Clinical Pharmacist, Acute Medicine, University Hospital Aintree. The Chair accepted apologies for the following: Dr Adit Jain, Joanne McEntee, Susanne Lynch (Jenny Johnston attending) and Paul Skipper (James Parker attending). The Chair formally expressed thanks to Donna Gillespie-Greene for all her hard work and for helping to make the APC a success.	
APC/19/59	Declarations of Interest and Quoracy Check	
	The meeting was quorate. There were declarations of interest for items on the agenda from Paul Gunson (Astra Zeneca) and Mike Welsby (Glaxo SmithKline).	
APC/19/60	Minutes of the previous meeting and matters arising	
	APC/19/60/01 – Minutes from the Previous Meeting The Minutes were agreed to be an accurate record of the previous meeting on 31 July 2019. APC/19/60/02 - Markey Arising	
	Items which should not be routinely prescribed in primary care – bath and shower preparations in paediatrics Catrin Barker is unable to attend this meeting, so it will be carried forward to October's agenda for an update. Multi-compartment compliance aids – update GR confirmed that this will go to the next Chiefs and CCG Leads meeting on 13 November. Declaration of Interest forms Declarations of Interest need to be renewed. Forms will be sent out to all APC members in the next 2-3 weeks. Members to look out for the email and return the form without delay. Target date for completion is the end of year.	CB AH/VZ
APC/19/61	New Medicines	
71 3/10/01	APC/19/61/01 – Fluocinolone for non-infectious uveitis – NICE TA590, red statement It is PBR excluded but NICE do not expect a significant financial impact. A brief summary of the statement was given. There were no questions and the red statement was agreed.	
	19/61/02 – Risankizumab for psoriasis – NICE TA596 (Fast Track), red statement This is a fast track NICE TA which the APC agreed to bring through in normal time scales. This was because several organisations felt they would be unable to turn it around in time and that there was no unmet clinical need that warranted earlier consideration of the NICE TA. It is now outside the 30-day fast track period. It is PBR excluded but NICE do not anticipate any financial impact. This statement was agreed by the APC.	
	19/61/03 – Psoriasis, sequential use of biological agents – update of existing document to add NICE TA596 This psoriasis statement has been updated to include NICE TA596, in line with the Risankizumab item above. The number of sequential biological agents that can be used has not been increased. The APC agreed the updated document.	
	19/61/04 – Sodium zirconium for hyperkalaemia – NICE TA599, red statement There are two indications that have been approved by NICE; for emergency care inpatient use for life-threatening hyperkalaemia, and for outpatient care for people with persistent hyperkalaemia and chronic kidney disease or heart	

failure. DT went through the details. The PAS only applies to secondary care, hence the red RAG rating, although it is not PBR excluded. NICE only consider this to be cost-effective if the PAS is applied, so prescribing must be retained by secondary care as no primary care rebate scheme is available. This could be a significant cost pressure for provider trusts. Aintree Hospital has had interest internally for using this, but DF reported that there has currently not been any interest in this from the heart failure team at LHCH. This statement was agreed by the APC.

19/61/05 – Ranibizumab for CNV (non-NICE indications)

This is a routine review of an expiring statement and required only minor updates. It covers use for choroidal neovascularisation (CNV) caused by indications not included in NICE TAs. With reference to the effectiveness information, JP reported that the supporting trial is now published and the statement has been updated to reflect this. Numbers of patients are low. It is proposed that this is a final update and it will be added to the static list. This was agreed by the APC. CCG leads agreed for the current CCG approvals to be carried over to the updated statement.

19/61/06 – Nalmefene for alcohol dependency – routine review of statement (for static list)

This is the second routine review of this statement since the NICE TA was published in 2014. There were no changes made. Previously the APC had agreed to approve this with individual CCG RAG status due to the different ways that alcohol services are commissioned around Pan Mersey. The APC agreed for this to be added to the static list and for CCG approvals to be carried over. AH requested that CCGs confirm the RAG status for their organisation when returning their CCG approvals to ensure that this continues to be reflected correctly within the Pan Mersey formulary.

19/61/07 - Cariprazine for schizophrenia - amber retained statement

This is a new second generation antipsychotic, licensed for schizophrenia. It is the only antipsychotic that has clinical trial evidence to support a positive effect on persistent predominant negative symptoms of schizophrenia, and is recommended for this patient cohort when they have failed to improve with other standard treatments. It was originally brought to APC in May as an amber initiated statement, but concerns were raised by GPs around the prolonged requirement for highly effective contraception and it was suggested that cariprazine should be amber retained RAG rating. After a lot of discussion, the APC asked the NMSG to re-consult as amber retained, with a further review at one year when clinicians have more experience of this drug. AH went through the details of the amber retained statement and the feedback from the second consultation. The APC was advised that it is important not to set a precedent for new drugs and the NMSG sought assurance that this should not set a future precedent for any drug requiring additional contraceptive precautions in pregnancy to be RAG rated differently to the agreed APC RAG criteria. The subgroup also asked for confirmation that commissioning issues should not be used as a reason to request that subgroups apply the RAG criteria differently to what is agreed, as this is considered to be implementation and therefore lies outside the remit of the APC.

After much discussion, the APC felt that this is a pragmatic decision and supported the amber retained statement, with review after one year. There is a patient cohort in Pan Mersey that need treatment, and the APC does not believe that this sets a precedent for future drugs. The APC considered cariprazine to be sufficiently different to other antipsychotics to justify an initial short-term difference in RAG status, with review after one year, and that this did not set a precedent. Subgroups should continue to apply the RAG criteria consistently.

JI advised the committee that in CWP, it was agreed in May that cariprazine would be prescribed by specialists for the first 12 months and then prescribing would be reviewed and evidence of effectiveness would be brought back to their medicines management group in March 2020. In terms of numbers CWP have had 3 patients prescribed cariprazine since May. JI is happy to feed back the findings from CWP to inform the review at one year, and the other mental health provider trusts have indicated that they will do the same. There were no objections and the APC agreed the amber retained statement,

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19/62/01 - Lithium paediatric RAG rating

with a review in 12 months' time.

It was noted that there was inconsistency in the Pan Mersey formulary which lists lithium as Purple for children aged 12-18 years, but this is not now included in the shared care framework.

On investigation, Alder Hey confirmed that they do not use lithium in paediatrics and other trusts said it would be used very rarely as other treatments would be used in preference.

Overall, the Shared Care subgroup felt that paediatrics should not be included in the shared care framework, recognising that there is a risk that shared care could be interrupted while a patient waits to transition from paediatric to adult services. There were no objections to this proposal in the consultation feedback. This change of RAG designation to Red for paediatrics was agreed by the APC.

19/62/02 - Riluzole shared care framework - amendment

This item was discussed at a previous APC meeting. The proposed amendment to the SCF allows for the specialist to request from the GP the transfer of prescribing and monitoring at 1 month instead of 3 months after initiating the drug in certain patients where it is very difficult for the patient to attend the specialist for this. Due to the restricted mobility and life expectancy of patients with amyotrophic lateral sclerosis, this is a particular issue with this drug. The APC previously asked for enquiries to be made around whether results from blood tests taken in primary care could be transmitted to the Walton Centre for monitoring, but this is not technically possible. No dose titration is involved, i.e. dose is stable, but there is a requirement for a monthly blood test for the first 3 months. There were concerns expressed regarding additional workload for GPs. However, it is always possible for a GP to decline to participate for an individual patient if they wish. The APC agreed to the amended statement.

19/62/03 Methotrexate shared care framework - amendment

Currently the SCF states effective contraception is required for men and women for a further 3 months after treatment, but the SmPC has now been changed to 6 months and it was proposed the Shared Care framework was changed in line with that. Feedback commented about who was responsible for giving contraception guidance, so information has been added to the Shared Care framework to clarify that this is shared between the specialist initially, and GP and specialist on an ongoing basis. Specialists had commented that the BSR guidance was unchanged (and in practice blood monitoring was done according to BSR guidance not strictly to the SmPC), but the subgroup felt in the case of pregnancy the SmPC recommendation should be followed. The EMIS system is mentioned for ordering a P3NP test, but it may be possible to use other systems. The subgroup will investigate and add those systems when this information is confirmed and will amend the wording to ensure the process is described accurately. The APC agreed to the change to 6 months as above and agreed that information on the P3NP test can be added with no need to come back to APC for approval.

APC/19/63 Fo

Formulary and Guidelines

19/63/01 – Methotrexate liquid formulary amendment

The liquid is not included in the Shared Care Framework for adults. Alder Hey may use it in paediatrics. It was proposed to amend the formulary to state that methotrexate liquid is for paediatric use only. This was agreed by the APC.

19/63/02 - Disease Modifying Drugs (DMD) formulary amendment

DMDs are designated Purple for adults and shared care frameworks are in place which do not include paediatric use. The majority are designated Red for children. However, there is an inconsistency in the formulary with sulfasalazine as it is designated Purple for children in chapter 1. The FGSG proposed amending sulfasalazine in chapter 1 to Red designation for paediatrics in line with all the other disease modifying drugs. This was agreed by the APC.

19/63/03 – Biologics in patients with flare of active inflammatory arthritis during pregnancy

There is currently a Pan Mersey policy covering use of biologic agents in preconception where conventional DMDs are contra-indicated in pregnancy. The proposed additional policy applies to women who are currently pregnant and previously did not require DMDs but have experienced disease flare requiring DMD treatment, but this is contraindicated. The policy proposes use of anti-TNF agents outside of NICE criteria (which require a trial of conventional DMDs prior to anti-TNF agents) in this circumstance. Incidents of patients who deteriorate in pregnancy are rare, with an estimated maximum of 10 patients per year in Pan Mersey area. Consultation feedback suggested that JIA should be included in the list of inflammatory arthritis, and this has been added. It was confirmed anti-TNF treatment should be stopped at the first specialist review after delivery, in line with the pre-conception policy. The APC agreed to the policy.

19/63/04 – Biologic therapy for treatment of psoriasis in patients who cannot attend for PUVA treatment

NICE TA guidance on individual biologic agents states that they can be used where patients are PUVA intolerant or have a contraindication. However, the NICE clinical guideline CG153 states, offer patients alternative second-line or third-line treatment, where accessing PUVA treatment is difficult for logistical reasons (for example, travel, distance, time off work or immobility). Southport and Ormskirk, and Royal Liverpool Trusts have identified a group of patients where access to PUVA is difficult (estimated 15 – 20 patients per year), but Wirral Hospital Trust appears to offer more extensive PUVA clinic times and do not consider this to be an issue. The calculation of cost difference if patients have biologic agents instead of PUVA is complex as prices of biologics vary significantly between agents, especially where biosimilars are available, and making assumptions on how many PUVA treatments a patient would have (max. lifetime 150 treatments) is problematic. The subgroup asked the APC for its view on whether it agreed NICE TA guidance should be followed in preference to clinical guidance, given that NICE clinical guidance is not mandatory, and whether it wished to consider the possibility that PUVA clinic availability should be expanded.

There was an extensive discussion covering: patients' varying definitions of lack of ability to attend PUVA; employer willingness to allow time off work; whether these cases can be considered under the IFR process (it was established that they could not be considered as an IFR); and that social circumstances are not taken into consideration when considering entitlement to treatment.

The question of what other areas in the UK are doing was raised. The APC asked the FGSG to research how other areas address this situation and bring this information back to APC in future for further consideration.

GR/ FGSG

19/63/05 - Formulary Chapter 7 review

A routine review of Chapter 7 has been conducted, including a merger of the Pan Mersey and Wirral formularies. A summary of changes was highlighted. The APC agreed to the proposed changes.

19/63/06 – Formulary Chapter 2 review

This was a review carried out to merge the Wirral formulary with the Pan Mersey formulary. A summary of changes was highlighted. The APC agreed to the proposed changes.

19/63/07 – Ciclosporin eye drops (Verkazia®) – vernal keratoconjunctivitis Consultation feedback was mainly in agreement or made no comment on the proposed amber retained statement. One comment suggested a red RAG designation, but the adult formulation (*Ikervis®*) is already designated amber initiated. The APC agreed to the amber retained statement for use in children and adolescents.

19/63/08 - Erectile Dysfunction guideline

Consultation feedback received was discussed. There were comments about daily tadalafil being designated black and that treatment for patients in severe distress is no longer permissible in England, with the exception of generic sildenafil.

Concern was expressed by GPs that if this document is intended for primary care prescribers then there is far too much information in it, and significant portions were repeated. They requested that, in order to make it more user-friendly, the document should be reduced, preferably to one page of information. The APC agreed that this guideline should be edited, with any repetition removed and reduced in size; this will then need to be sent out for reconsultation and brought back to APC for approval.

GR/ FGSG

19/63/09 - Perampanel liquid

The proposal to add the new perampanel oral suspension to Chapter 4.8.1 as amber recommended for adults and amber initiated for paediatrics, was agreed. This is for adult and paediatric epilepsy patients for whom tablet formulation is unsuitable.

19/63/10 - Iloprost injection

A licensed formulation has become available, so it was proposed by the subgroup to substitute this in the formulary for the unlicensed product, retaining the red RAG designation. There is a small cost increase. The APC agreed to this proposal.

19/63/11 – Relvar Ellipta inhaler (fluticasone furoate / vilanterol 92 micrograms/22 micrograms) inclusion in adult asthma guideline
It was proposed to add this to the "additional add on therapies" section as an alternative to other preferred inhalers where the patient must have once daily dosing. However, a member suggested that this should also be added to the "initial add-on" section as well, because BTS classes Relvar Ellipta 92/22 as a low-to-medium dose inhaled steroid. The APC agreed with this suggestion. The quideline was agreed subject to the above amendment being made.

19/63/12 – Steroid +antibiotic eye drop – RAG designation clarification
Some hospitals prescribe these in the post-operative period. Patients have
been dispensed drops in hospital and not realised that it is a short-term
treatment and occasionally they go to their GP to ask for a further supply.
Therefore, in order to provide clarity for GPs, the APC agreed to clarifying
wording in the formulary to state that corticosteroid+antibiotic combination eye
drops should be prescribed in hospital only, and that such use is designated
red.

	19/63/13 – Testosterone deficiency in women – grey statement Testosterone preparations are currently not licensed for this indication. Some sexual health specialists suggest testosterone treatment for women and ask GPs to prescribe, and a business case has previously been sought but has not been forthcoming. The subgroup suggested a grey statement be issued in the interim. It was agreed to remove the sentence "NHS England expects GPs to co-operate with an NHSby the GIC". The APC thought that there should be a formal application for this from specialists and accepted that the grey statement is the first step in that process. The grey statement informs GPs that prescribing for this indication has not yet been approved by APC. The APC agreed to this grey statement.	
APC/19/64	APC Reports	
	APC/19/64/01 – NICE TA adherence checklist August 2019 – for noting For noting. This has been updated to end of August 2019. APC/19/64/02 – RMOC newsletter Issue 6 – for noting.	
APC/19/65	Any Other Business	
	None.	
APC/19/66	Date, Time and Venue for the next meeting	
	Date and time of next APC meeting:	

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