



Pan Mersey Area Prescribing Committee

14:00 – 16:00 hours Wednesday 22 May 2019 The Education Centre, Kent Lodge, Broadgreen Hospital, Thomas Drive, Liverpool, L14 3LB

Minutes

Members	Organisation(s)	Present
David Ainscough	Pharmacist, Mersey Care, Liverpool and South Sefton Community Services Division	X
Anna Atkinson	Deputy Lead Pharmacist Meds Man, Lancashire Care NHS FT	X
Catrin Barker	Chief Pharmacist - Alder Hey Children's NHS Foundation Trust	X
Dr Rob Barnett	LMC Representative / GP, Liverpool	X
Dr Ivan Camphor	LMC Representative, Mid-Mersey	X
Neil Chilton	Medicine Management Clinical Services Manager North West Boroughs Healthcare NHS Foundation Trust	X
Alison Evans	Lead Medicines Management Pharmacist, Wirral University Teaching Hospital NHS FT	X
Danny Forrest	Deputy Chief & Cardiology Pharmacist, Liverpool Heart & Chest Hospital	X
Andrea Giles	Pharmacist, St Helens CCG	X
Dr Adit Jain (Acting Chair)	Clinical Lead, Prescribing – Knowsley CCG	Х
Jenny Johnston	Senior Pharmacist, South Sefton CCG / Southport & Formby CCG	X
Barry Lloyd	Pharmacist – West Lancashire CCG	X
Jenny Lunn	Senior Medicines Optimisation Lead – Warrington CCG	X
Fiona McFall	Interim Senior Pharmacist, Knowsley CCG	X
Dr Hilal Mulla	GP, Southport & Formby CCG / South Sefton CCG	X
Agatha Munyika	Pharmacist, Mersey Care NHS Trust	X
Dr Shankara Nagaraja	Consultant Intensivist/Anaesthetist, University Hospital Aintree	X
Kathryn Phillips	Medication Safety Officer, Bridgewater Community Healthcare NHS FT	X
Rachael Pugh	Prescribing Advisor, Wirral Medicines Management Team, MLCSU	X
Sarah Rafferty	Head of Pharmacy Services, Mersey Care NHS FT	X
Lucy Reid	Head of Medicines Management – Halton CCG	X
Paul Skipper	Deputy Director of Pharmacy, RLBUHT	X
Dr Matthew Van Miert	Consultant Anaesthetist, Wirral University Teaching Hospitals NHS FT	X
Mike Welsby	Pharmacist, St Helens & Knowsley Teaching Hospitals NHS Trust	X
Catherine Witter	Medicines Information Pharmacist, Southport & Ormskirk Hospital	X
Attendees	Organisation(s)	Present
Helen Dingle	Senior Prescribing Advisor, MLCSU	X
Kieron Donlon	Senior Prescribing Advisor, MLCSU	X
Anne Henshaw	Senior Medicines Commissioning Pharmacist, MLCSU	X
Graham Reader	Senior Medicines Commissioning Pharmacist, MLCSU	X

APC/19/30	Welcome and apologies	Action
	The Acting Chair for this meeting was Dr Adit Jain.	
	The Chair welcomed members and accepted apologies from the following:	
	Dr Sid McNulty, Dave Thornton, Dr Omar Shaikh, Daniel Collins, Paul Gunson	
	(Fiona McFall attending), Carrie Barton, Peter Johnstone, Susanne Lynch	
	(Jenny Johnston attending), Nicola Cartwright (Andrea Giles attending),	
	Dr Anna Ferguson (Dr Hilal Mulla attending), Nicola Baxter (Barry Lloyd	
	attending), Gill Gow, Joanne McEntee and Donna Gillespie-Greene.	

APC/19/31	Declarations of Interest and Quoracy Check	
7 0,10,01	A quoracy check confirmed that this meeting was quorate.	
	There was one declaration of interest from DF (Astra Zeneca).	
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APC/19/32	Minutes of the previous meeting and matters arising	
	APC/19/32/01 – Minutes from the Previous Meeting The Minutes were agreed to be an accurate record of the previous meeting on 24 April 2019.	
	APC/19/32/02 – Matters Arising Freestyle Libre Meeting - update	
	The meeting on flash glucose monitoring with provider and commissioner stakeholders, as discussed at a previous APC meeting, took place on 1 May 2019. Agreement was reached on a proposed amended statement and template supporting documents, in light of recently published NHS England criteria for use, and these will be going on the APC consultation email at the end of May. These amendments include additional occupational, psycho-social and impaired hypoglycaemia awareness criteria. The view expressed by specialists at the meeting was that approximately 50% of people with type 1 diabetes could fit the NHS England criteria. NHS England temporary funding will only cover 20% of people with type 1 diabetes using flash glucose monitoring. The statement and supporting documents will be brought back to APC after the normal consultation process, with July as the earliest possible date.	GR
	APC Chair – update GR thanked Dr Jain for offering to be Acting Chair for this meeting, and attendees agreed to this. Since the April APC meeting, discussions have taken place and Dr Adit Jain and Peter Johnstone have offered to share the position of Committee Chair, and Dr Anna Ferguson offered to act as Deputy Chair. The meeting attendees agreed with this arrangement and it was agreed to email all Committee members explaining these proposed new arrangements, to ensure all were in agreement. The email would state that agreement would be assumed from those not present unless otherwise stated by 7 th June 2019.	
	Opioids – Brand prescribing with generic name – update KD confirmed that he is still chasing Davina Halsall (CDAO) for an opinion on the need to include both the brand and generic name on prescriptions. He will bring an update to the next meeting and will hold back the document until a response has been received. JL and LR to raise at the CD LIN meeting tomorrow afternoon.	JL/LR
APC/19/33	New Medicines	
	APC/19/33/01 – Grey statement summary Grey 'holding' statements have been produced for the following: Alirocumab solution: For reduction of cardiovascular risk in adults with established atherosclerotic cardiovascular disease. To be reviewed if a formal application for use is received and prioritised. Prasterone pessaries: For vulvar and vaginal atrophy. To be reviewed if a formal application for use is received and prioritised. Sodium Zirconium Cyclosilicate: For hyperkalaemia in adults. Will be reviewed when the NICE TA is published (expected August 2019). Risankizumab solution for injection: For moderate to severe plaque psoriasis. Will be reviewed when the NICE TA is published (expected August 2019).	
	APC/19/33/02 – Non-renewal of NMSG statements April-September 2019 Two groups of drugs listed. The first 7 drugs are all hospital-only, NICE TA, PBR excluded drugs. At the end of the 2-year life, if the NMSG consider the	

Red statements do not add any further additional benefit because the recommendations are established into clinical practice, then they will be archived at expiry and a link to the NICE TA retained in the relevant formulary entries.

For the second group of drugs on the list (Glargine + lixisenatide for type 2 diabetes and Abatacept for psoriatic arthritis), a Grey statement was produced at launch. No interest has been shown within 2 years so the two statements will be archived at expiry and the drugs will remain as Grey in the formulary.

The above actions were agreed by the APC for all drugs listed.

APC/19/33/03 – Tildrakizumab for psoriasis – NICE TA575, Red statement A Red statement has been produced in line with the NICE TA and a brief summary was given to the committee. There were no questions and the APC agreed the statement.

APC/19/33/04 – Certolizumab for psoriasis – NICE TA574, Red statement A Red statement has been produced in line with the NICE TA. A summary was given to the committee. There is no significant resource impact anticipated. The APC agreed the statement.

APC/19/33/05 – Psoriasis, sequential use of biological agents – update of existing document to add new NICE TAs

This has been updated in line with the two statements above. Sequential options remain limited to three in the guideline as the new drugs fit into existing pharmacological categories. This is in accordance with the precedent agreed at previous APC meetings whereby additional biologic agents have been recommended by NICE with the same criteria and are within existing pharmacological categories.

The APC agreed the updated guideline.

APC/19/33/06 – Cariprazine for schizophrenia – Amber Initiated statement This is a new second generation antipsychotic. Although licensed for schizophrenia, the NMSG recommends it is positioned for specialist initiation as a non-first line treatment option for patients with predominant negative symptoms of schizophrenia when existing antipsychotic treatments are ineffective or unsuitable. This is based on its unique pharmacology and is felt to be the cohort of patients where there is a significant unmet clinical need and best value could be derived from the use of cariprazine. Expected patient numbers are low and patients would typically have tried amisulpride first. The NMSG proposed an Amber Initiated RAG rating, consistent with other atypical antipsychotics, as the drug was not felt to substantially differ in terms of monitoring requirements. It was acknowledged that some of the stakeholder feedback suggesting Amber Retained RAG was due to historic issues and commissioning arrangements in some areas and that discussions are already underway to try to resolve these.

There is no available data on the use of cariprazine in human pregnancy but animal studies have shown teratogenicity. The prolonged half-life of one of the active metabolites of cariprazine infers a projected risk of teratogenicity due to the length of exposure, therefore highly effective contraception should be used throughout treatment and continued for 10 weeks after stopping cariprazine. This has been licensed in the US since 2015 and there have been no warnings or issues reported from there. The prescriber-initiator is responsible for identifying and taking the appropriate action regarding any drug interactions with existing medication, ensuring highly effective contraception is started if required, titrating and stabilising the dose and monitoring the patient during this time.

The LMC representatives raised concerns about the Amber Initiated RAG rating and suggested that Amber Retained would be more appropriate. IC stated that GPs are not equipped to increase the dose and that this is a specialist drug and it would be dangerous or even negligent to use this in GP practices. RB supported the Amber Retained RAG and felt that the additional contraception warnings and lack of experience with this novel drug would mean not many GPs would be willing to take on prescribing at this stage without the patient being retained by the mental health service.

The concerns were acknowledged and it was reiterated that Amber Initiated means that initiation and dose titration is the responsibility of the initiating specialist clinician and GPs should not be asked to take over prescribing until the dose is stable. Concerns were raised by a few committee members that many new drugs become available each year that GPs would have limited experience of and that this would set a precedent of not following the agreed RAG criteria just because a drug is new. It was questioned why this should be treated differently to any other Amber Initiated drug just because it is new. RB said that GPs would be happy to prescribe lots of new drugs but it is his view that this drug different. He proposed that an Amber Retained RAG could be reviewed earlier than normal, e.g. after 12-18 months, at which point GPs might be more comfortable to take on prescribing.

The representatives present from the specialist mental health services acknowledged that this is a chronic condition but advised that if all patients are retained within the service then they do not have the capacity to review all the patients who are stable and that this would mean that waiting time for new patients or those needing specialist support would be further extended. NC advised that patients who are discharged are still able to go back in to the specialist service if they need to.

HM agreed with the sentiments expressed by the LMC representatives and explained that GPs in Sefton have difficulties in accessing mental health services rapidly when these patients deteriorate which is why Sefton would want all atypical antipsychotics, including cariprazine, to be Amber Retained. AH reported that the NMSG were aware of the issues when discussing and proposing the RAG rating. The concerns about pregnancy were looked into extensively and the NMSG established that this is not the same as valproate. The licensing process now requires a risk reduction plan for any new drug where there is no information regarding use in human pregnancy, which is much more stringent than it was historically. There is no evidence of teratogenicity in pregnancy and cariprazine has been available in the US since 2015 with no warnings or reports of issues, which is reassuring. There is no additional drug monitoring over other atypical antipsychotics and the NMSG concluded that cariprazine wasn't sufficiently different to warrant a different RAG rating. AH had spoken to SL regarding the Sefton situation and it was accepted that this may be Amber Retained there until the discussions between Mersey Care and Sefton are concluded. However, SL did not feel that this should prevent cariprazine from going through APC as Amber Initiated as they acknowledged that this was a local commissioning issue for Sefton to resolve outside of APC.

It was also acknowledged that it is difficult to separate out monitoring for the drug and for the condition, but the general feeling within NMSG was that the patients suitable for cariprazine are unlikely to be discharged to primary care in the immediate future due to the nature of the patients. HM stated that patients on antipsychotics are frequently discharged to primary care, often before they are fully stable, and that this is where the problems have arisen. JL raised a concern that there are some CCGs who are working with the local mental health trust to put suitable arrangements in place to support discharge of stable patients and free up specialist service capacity for new patients and an Amber Retained RAG would prevent them from being able to progress with this. Different CCGs are at different stages of agreeing the local commissioning arrangements.

The Chair asked if the RAG rating could be changed to Amber Retained and brought back for review in 6 months. AH advised the committee that they would need to re-consult on the RAG change and that there is a risk of an impasse if those stakeholders in agreement with Amber Initiated feed back that they do not support Amber Retained. AH offered the alternative of moving forward with Amber Initiated in line with other antipsychotics but accept that in some CCGs it will only be ratified as Amber Retained and this could be reflected within both the statement and the formulary. That way it does not preclude some CCGs who want to move forward with Amber Initiated but allows others to state it is Amber Retained for their patients. There is already a precedent for this with other drugs.

CB proposed Amber Retained for now, but it should be re-consulted on in 12 months' time. DF supported this on the basis that GP representatives are opposed to the Amber Initiated RAG and that GPs will not prescribe if they don't feel supported by the specialist service. PS suggested that the APC needs to be clear on how it has made that decision and asked if this should go to a vote. NC stated that there will be little use of this new drug and expressed a concern that 12 months may not provide much additional experience to be able to reconsult on it. However, he would support a temporary Amber Retained position in order to move things forward.

The Chair concluded that this should go back out for re-consultation as Amber Retained and this should be reviewed in 12 months. There was no objection to this proposed course of action from those members present.

Following the meeting, the chair on reflection recognised that deciding this course of action, whilst not objected to by committee members present, could have been put to a vote first.

APC/19/33/07 – Ticagrelor for ACS & preventing atherothrombotic events post-MI – routine review of Amber Initiated statement

This is a routine review of the existing statement. The main change is around the switch to the extended 60mg twice daily dose after 12 months at 90mg twice daily. The initial intention was that secondary/tertiary care would perform this switch at 12 months, however in practice this is not proving to be feasible. This document proposes that a simple review is undertaken in primary care at 12 months, at which point the switch to 60mg twice daily for a further three years is made.

DF acknowledged the concerns raised in the stakeholder feedback and explained that the 12-month review was never intended to be a full Cardiologist review, but a simple review by a Cardiac Nurse working within a multidisciplinary team and then making the switch to 60mg twice daily. A support resource has been developed to assist GPs in undertaking this check at 12 months for those who wish to use it. This is no different to the routine checks that should be made for any other extended antiplatelet use. DF reiterated that responsibility for identifying patients suitable for extended ticagrelor remains with the specialist at the point of index event.

AJ believes it is important for there to be a proper hand-over to GPs. Whilst the drug is commonplace now, GPs would appreciate clear guidance in respect of the duration of treatment and at what point the switch to 60mg needs to be made. AH to highlight the last sentence on page1 in bold font to emphasise this point. DF advised that this will be audited within LHCH and will be followed up if it is found that this is not being adhered to.

The APC agreed the statement.

APC/19/34

Shared Care

APC/19/34/01 – Sodium valproate RAG rating

At the January meeting, the APC suggested that the RAG rating for women of childbearing age should be designated Amber Retained. The Shared Care Subgroup sent this out for consultation. The majority of the feedback was

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supportive, but one comment suggested it could be Red as patient numbers are small. These patients require an annual review with the specialist so Amber Retained is the most appropriate RAG rating.

The APC approved this amendment to the Pan Mersey formulary.

APC/19/34/02 – Degarelix formulary amendment – for information

Pan Mersey has already agreed that the first two doses of degarelix are administered by secondary care. In Wirral, the first dose is administered in hospital then the patient transfers to primary care. This difference is to be noted on the formulary entry. There is an ongoing review of the formulary chapters to align the Wirral formulary with the Pan Mersey formulary so this may be reviewed again when the Chapter is reviewed. The APC noted these actions.

APC/19/35 Formulary and Guidelines

APC/19/35/01 - Tolvaptan in SIADH red statement

Although this was proposed as a Red drug, it is PBRe tariff excluded so the cost is recharged to CCGs. A summary of the statement was given, and the consultation feedback has been addressed. Usual course of treatment is 3-4 days. The expected cost across Pan Mersey is less than £1,000 per 100,000 patients annually with slight variation from year-to-year dependent on exact patient numbers.

The APC agreed to the statement.

APC/19/35/02 - Medical devices - formulary entries

PrescQIPP has listed a number of <u>recommendations</u> on whether or not various devices should be prescribed in primary care, or recommended criteria for their use. FGSG proposed formulary positions on relevant devices based on this list and produced a table outlining these. Consultation feedback was largely in agreement.

Prontaderm bacterial de-coloniser is proposed as designated black, but Aintree hospital currently uses this in its decontamination policy but will consult with its infection control department and raise any concerns with the FGSG if these arise.

It was confirmed that anal irrigation systems, although in the PrescQIPP list, are being dealt with by CCGs as part of a separate commissioning policy which will be concluded by July, and the formulary will reflect this at that time.

The APC agreed to the list of actions in the table to be implemented in the formulary.

APC/19/35/03 – Blood glucose meter guideline

The current guideline is based on a blood glucose meter assessment published by Greater Manchester MMG in 2016 and it is due for review. However, GMMMG has no plans to update this assessment and so the FGSG has updated the current guideline by assessing all <£10 per 50 strip blood glucose meters, including ones made available after the previous guideline, and recommended the top-10 scoring meters as preferred choice meters as before. The Greater Manchester MMG scoring system and methodology were used (with their consent). Consultation feedback was extensive, but much was because people were worried that the guideline prevented them using nonpreferred choice meters, which is not the case. The subgroup view was that 10 meters on the list allowed sufficient choice for most patient preferences to be accommodated but doesn't rule out use of others if necessary. It was also confirmed that prescribers do not have to switch patients who are using blood glucose meters <£10 per 50 strips that are no longer preferred choice options for the sake of it, as this guideline is for new patients or for patients switching from meters using strips costing >£10 per 50 strips. The APC agreed to the guideline.

	APC/19/35/04 – Acetylcysteine (NACSYS) – addition to formulary An application was received to add this to the formulary, designated Green, as an alternative to carbocisteine in accordance with NICE COPD guideline. Consultation feedback was in agreement. It has a simpler dosage than carbocisteine and is likely to be less costly. It has to be prescribed by brand name, as prescribing generically will result in increased costs. Use in interstitial pulmonary fibrosis will remain designated black. This addition was agreed by the APC.	
	APC/19/35/05 – VSL#3 sachets This is a poly-biotic formulation used to treat pouchitis, but it has recently been removed from the Drug Tariff and so can no longer be prescribed in primary care. If hospitals wish any patients to continue using this then they will have to continue to prescribe internally. The APC agreed to the proposal to designate this as black.	
APC/19/36	APC Reports	
	APC/19/36/01 – NICE TA Adherence Checklist April 2019 For noting. Completed to end of April and will be available on the website. APC/19/36/02 – RMOC Newsletter 2019: issue 3, issue 4 – FOR NOTING This is a standing item on the APC Agenda. There were no items of note to specifically highlight at this meeting.	
APC/19/37	Any Other Business	
	APC/19/37/01 – Freestyle Libre statement JL reported that technical changes had been agreed to this document at the March APC meeting, as the DVLA had stated flash glucose monitoring was now permissible to fulfil driving requirements for patients with diabetes on insulin. These agreed technical changes had not been recorded in the minutes or in the APC report in March, and JL requested that they were included in the APC report of this meeting for completeness. The Committee agreed to this.	GR
APC/19/38	Date, Time and Venue for the next meeting	
	Date and time of next APC meeting: The next meeting will be on Wednesday 26 June 2019 at 2.00-4.00pm Venue: The Education Centre, Kent Lodge, Broadgreen Hospital, Liverpool, L14 3LB	

The agenda and minutes of this meeting may be made available to public and persons outside of The Pan Mersey Area Prescribing Committee Health Community in order to comply with requests made under the Freedom of Information Act 2000.