

PAEDIATRIC MEDICINES MANAGEMENT COMMITTEE

Meeting held on 4^{th} May 2022 at 1pm Pharmacy Board Room, 4^{th} Floor, Oxford Road Campus & via MS Teams

Minutes

Core Represen	tatives	Name	Initials	
AMD for Quality and Safety RMCH and MCS (Chair)				
Professional Secretary and Medicines Information Pharmacist				
Deputy Chief Pharmacist, Medicines Optimisation and Governance				
Head of Medicines Optimisation and Governance				
Highly Specialis	ed Clinical Pharmacist-Paediatric Medicine			
Central Manchester CCG, GP				
Lead Medicines Information	Optimisation Pharmacist- Adult MMC/Medicines			
Divisional/Clini	cal Representatives (Clinical Speciality Units)			
NICU Consultan	t ·			
Consultant Paediatric Anaesthetist				
In attendance				
Women's and Children's Pharmacist				
Community Medicines Optimisation Service				
Medicines Optimisation Pharmacist				
Pharmacy & Oncology - Willow Inpatient Module Lead & Specialist Paediatrics Pharmacist				
Senior Medicines Optimisation Pharmacist, MHCC				
Consultant Paed	diatric Surgery			
MO Coordinator				
53,22	Apologies for Absence			
54.22	Declarations of Interest Nil			
55.22	Minutes of the Meeting held 6 th April 2022			
· .'	Amendments required:	•		
	Make clear that the meeting was not quorate			
	Minutes to be reviewed and amended outside of the meeting and re-circulated.			
Matters Arising				
56.22	Mexiletine – switch to licensed products Lead Pharmacist-High Cost Drugs and Homecare			
	Previously, we have been using an unlicensed version of mexiletine however it is now available as licensed capsule products. This does not have a significant impact in paediatrics, more in adults but has been submitted to PMMC for completeness.			

Inighlighted the cost impact – new version is 4x the amount of the unlicensed version, but this is not a significant cost pressure in paediatrics. raised concerns with tree the Hive impact because the proposal is quite complex in terms of how it will be prescribed in relation to the brand name for one of the products as one is expressed as a salt and the other as a base and so wanted to know how this could be built into the system. is going to look into this but thought that the best option would be to state that it will need to be prescribed by brand which reduces the risk of miss-selection. Committee agreed with the proposal, and and will pick up the Hive aspects outside of the meeting. Guidelines approved outside of the meeting 57.22 PMMC Professional Secretary The following items have been approved by chairs action outside of the meeting: -Palivizumab for RSV in infants - Guideline and Patient Specific Direction -Everolimus for Refractory Seizures with tuberous sclerosis complex guideline -Therapeutic Drug Monitoring in Children and Neonates -Policy updated - PGD Policy, IMP Policy, Medicines Policy, CD Policy All of the above were formally noted and approved by the Committee -NWTS-Guidelines for Management of Severe and life-threatening Bronchiolitis - GM to follow up before formal approval can be noted New Drugs New drug application for Labinic (probiotic) for high-risk preterm infants to prevent 58,22 necrotising enterocolitis and ratification of guideline Rotational Pharmacist/ Lead Pharmacist for Neonatal services This item was discussed at the last meeting and comments noted in the draft minutes circulated with this agenda however the meeting was not guorate. team are aware of the comments raised by the Committee at the last meeting, and it was agreed that this item could now be approved providing the minor amendments have been addressed. will review outside of the meeting once these have been made. Individual Patient Requests Individual Patient Request for Infliximab, HS-05422541 59.22 **Consultant Gastroenterologist** Individual Patient Request for Vedolizumab, LAH-04783724 60,22 Consultant Paediatric Gastroenterologist The Committee deferred approval of this application, pending clarification on the following:

NHS Foundation Trust	
	 Clarification of review criteria at week 14 – what specific outcomes will be assessed or measured, and under what circumstances would treatment be stopped, continued, or dose escalated. Financial sign off from directorate accountant.
61,22	IPR Tracker May 2022
01.22	Tracker noted.
Guidelines	
62.22	Amended Overactive Bladder Guidelines Consultant Paediatric Urologist
	Previously discussed and deferred with the following recommendations: - Baseline ECG and U&E requirements could be removed (noting that use if cautioned in hepatic and renal impairment, however) - The guideline should state that there should be no expectation that GPs will continue prescribing and monitoring of this medicine, but may agree to do so in exceptional circumstances - Keep baseline and regular monitoring of BP and HR - Resolution on where this ongoing monitoring is done can be determines outside of the PMMC meeting-members suggested exploring the possibility of local hospitals doing this, or perhaps development of a shared care protocol - Above amendments should be done on the most up-to-date version of this guideline
	Some of these amendments have now been made however noted that section 4.2.4 is still misleading in relation to where the monitoring responsibility sits. It was agreed that 'or with GP/Community' should be removed from this section.
	methylphenidate as this is off license. It would be useful for parents to have some tailored information because if they are provided with the actual SPC which talks about the licensed indication which is ADHD and some of the side effects, it could be alarming and inappropriate parents. Dadvised that it would be worthwhile sharing this document with the community continence team who pick up many of the initial referrals from primary care and they may choose to liaise with secondary care or back to the GP just so they are sighted to this particular guideline.
	It was agreed that will make the outstanding amendments. It wasn't thought that the PIL would be a barrier to approval at this point once all reference to GP/Community have been removed.
63.22	Epidural protocol and guidelines Lead Nurse Specialist – Children's Pain Team
	This document merges two previous documents: -Epidural Analgesia in Children (guideline for levobupivacaine with or without clonidine or fentanyl additive) -Epidural Analgesia in Children (protocol for levobupivacaine with or without clonidine or fentanyl additive)
	highlighted that no significant changes have been made to the information within the two documents that have been merged. This item was also discussed at the non-quorate meeting last month and was approved in principle awaiting final approval from this meeting.
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	NHS Foundation Trust	
	Approved	
64.22	Guideline updates-Calvive discontinuation Rotational Pharmacist RMCH & SMH	
	Calvive is being discontinued and it is referenced in a number of guidelines which have all been amended to provide a suggested alternative.	
	The Committee also suggested that if CALVIVE is now permanently discontinued, that recommendations about use of this product could be removed completely.	
	moted that one of the guidelines; Metabolic bone disease in prematurity is not a guideline that has ever been through PMMC but has been through NICU internal processes and therefore suggested that the amendment is submitted to the original ratifying body for approval.	
	It was also noted the other two guidelines are out of date and therefore the committee requested that the feedback is explicit in stating that only the amendment has been approved and the guideline in its entirety will still need to be reviewed on its original review date.	
65.22	Amendment to paediatric critical care continuous infusions guideline Specialist Paediatric Pharmacist for Neurology & Neurosciences	
	Amended monograph for Dinoprostone to state that the infusion can be given either centrally or peripherally. Previously the guideline stipulated that the infusion must be given centrally if 'high strength' however this is not an evidence-based recommendation. This change will mirror practice at SMH NICU.	
	This amendment was approved by the Committee however it was noted that this guideline is out of date and therefore only the Dinoprostone section has been reviewed and approved, and the rest of the guideline still requires review.	
66.22	Guideline for Paediatric Critical Care Intravenous (IV) / Inhalational Sedation for Procedures in Children	
·	Consultant PICU/ST7 Academic Trainee in Anaesthesia	
	The Committee felt that in order to be approved this guideline needs to be more explicit and consistent throughout about which patients, and which areas, that this document applies to-there are references to theatres however appendix 2 is an ED document.	
	with "guideline for" as this makes searching for documents in alphabetised lists difficult - agreed.	
	It was also noted that this document references a sedation policy that could not be located. and informed the Committee that an overarching paediatric IV sedation policy had recently stalled whilst being drafted, and that work was underway within RMCH to decide a strategy for safe IV sedation across the MCS.	
	A decision to approve this item was deferred pending the amendments noted.	
Policies		
67.22	Potassium Intravenous Policy Medicines Governance Pharmacist	
	For noting	
Other		
68.22	GMMMG guidance on transfer of prescribing responsibilities-consultation	
	Circulated for comments	
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Any Other Business

Voxelotor EAMS

Fast track application for Voxelotor for the treatment of haemolytic anaemia due to sickle cell disease in adults and paediatric patients, 12 years of age and older as monotherapy or in combination with hydroxycarbamide. Supply will be via clinic. Small cohort. Already added to pharm assist by adult team.

Form states outpatient prescription however specialist pharmacist is aware that it will need to be prescribed via inpatients to clinic however it is not clear on the form.

has updated the consent form for paediatrics.

Approved

NICE Tracker May 2022

TA769 Palforzia – Still awaiting an update re this item. noted that this is now at 3 months post issue. TA735 Tofacitinib – update required

to pick both items up outside of the meeting

NHSE Tracker May 2022

SSC2358 - tracker states 'not required at RMCH' however we have since merged with NMGH and we are aware that there is a cohort of paediatric HIV patients. advised that we get clarity from on this as committee were unclear who would pick this up from a pharmacy perspective? ID team or paediatric team.

Tocilizumab FoC IPR

The Committee did not feel that they have the correct expertise in this forum to review IPRs such as this where there is a lack of published evidence to evaluate the clinical effectiveness of treatment. In the protection of the challenges faced with IPRs that we are receiving from a paediatric point of view which has highlighted through MOB previously. It has been highlighted that an increased number of requests do not fit within the remit of the ToR of PMMC. One of the concerns raised with the tocilizumab requests as with others previously is that there is very little clinical evidence of effectiveness for this particular indication.

Agreed that these requests need to go to another forum where the less evidence-based requests would be able to go to that has appropriate representation and discussion around some of the ethical issues that they raise to pick up outside of the meeting what the interim plan is in the absence of the proposed forum.

Bevacizumab IPR

IPR to start bevacizumab has a poor prognosis in general, 2% overall survival rate following relapse. With chemotherapy we follow protocol or national guidelines that give recommendations on which chemotherapy to use and there was a document published August 21 for this indication which notes the BECON trial and although the trial is no longer recruiting it suggests a combination of bevacizumab, irinotecan and temozolomide and preliminary results published are encouraging and indicates that the addition of bevacizumab improves overall survival and progression-free survival rates. Bevacizumab, however, is not covered by the cancer drugs fund or NHSE and so the focus of this application is approval for funding.

The Committee approved this application but noted that financial sign off is required.

Date of the next meeting

Wednesday 1st June 2022 – 1pm to 2.30pm Pharmacy Board Room, 4th Floor, Oxford Road Campus / MS Teams