Drug and Therapeutics Committee – Minutes – Confirmed

Date / Time	Thursday 14th March 2019 8:15am – 10:00am
Venue	Seminar Room 6, Clinical Skills Building, HRI
Chair	Prof A Morice, Chair, Professor of Respiratory Medicine
Notes / Action Points	Mrs W Hornsby, Senior Pharmacy Technician
Quorate: Yes / No	Yes
Attendance	Mr S P Gaines, Professional Secretary, Senior Principal Pharmacist – Clinical Services Mr P O'Brien, Deputy Chief Pharmacist Mr D Corral, Chief Pharmacist, Clinical Director Therapy & Therapeutics Mr K McCorry, Medicines Optimisation Pharmacist, NECS (via phone link) Prof M Lind, Vice Chair, Professor of Oncology Dr A Samson, Infectious Diseases Consultant
Apologies	Dr S Raise, GP ER CCG Dr H Klonin, Consultant Paediatrician Mr R Kapur, Vascular Surgeon Dr O Ogunbambi, Consultant Rheumatologist

Agenda No	Item	Discussion	Decision Made	Action	Lead	Due Date	Progress /Date Closed
2019.03.01	**Apologies**	As above.					
2019.03.02	**Declarations of Interest**	None.					3/19
2019.03.03	**Minutes of the previous meeting**	Accepted as a true record.					3/19
2019.03.04	**Action Tracker**	**Tracker** ARIA request forms have now been received for atezolizumab, which cover TA520/492/525.	Action complete.	No further action			3/19
		Out of Hours Flowchart Flowchart has been updated but further amendments are required. Discuss next time.	Ongoing.		DC	11/18	
		Tracker – Erenumab Minutes from Hull & ER CCG have not yet been sent to HUTH. KMcC will chase.	Ongoing.		KMcC	3/19	
		Tracker – Erenumab WH has added FOC document to agenda.	Action complete.				3/19
		New Product Requests AM has written to applicants and WH has updated formulary.	Action complete.				3/19
		NICE Guidance WH has added TAs to back of formulary.	Action complete.				3/19
		Prescribing Guidelines AM has written to Prof Maraveyas regarding VTE guideline.	Action complete.				3/19
		Items Which Should Not Be Routinely Prescribed SG has liaised with the senior Pharmacists for Renal and	Action complete.				3/19

		Cardiology regarding aliskiren.					
		Items Which Should Not Be Routinely Prescribed Document already discussed at HERPC, so not added to HERPC agenda.	Action complete.				3/19
		DSU AS has highlighted systemic and inhaled fluoroquinolones associated risk of aortic aneurysm to ID colleagues.	Action complete.				3/19
		DSU AM has discussed sildenafil with PH team.	Action complete.				3/19
		DSU WH has discussed adding risk of severe burns with emollients to HERPC agenda but AR felt topic had already been sufficiently covered.	Action complete.				3/19
		DSU AS has discussed direct acting antivirals for chronic hep C - risk of hypoglycaemia in diabetic patients with ID colleagues.	Action complete.				3/19
		DSU SG has discussed the risks associated with use of hydrocortisone buccal tablets with AK. On investigation, HUTH were using this in some patients. In response, a line extension for hydrocortisone granules has been added to the agenda for discussion today.	Action complete.				3/19
		DSU Ipilimumab: reports of CMV GI infection. ML still to discuss with colleagues.	Ongoing.		ML	3/19	
		Formulary Review WH had updated published formulary.	Action complete.				3/19
		RMOCS KMcC informed the committee that NECS are already looking into prescribing of liothyronine in the community. POB informed the committee that West and North Yorkshire CCGs had written a statement based on RMOC, which he would share with KMcC, with a view to adopting it for Hull & ER.	Action complete. POB to send statement to KMcC.		 POB	 4/19	3/19

2019.03.05	**New Product Requests**	**Aprotinin – Prof M Loubani & Dr A Vijayan** The product was removed from the Trust formulary in 2007, after the marketing authorisation was suspended. This followed publication of the BART study preliminary results. However the EMA review (EMA/590581/2013 on 18/09/2013) concluded the BART study was flawed and had serious methodology issues. Later analysis of other randomised clinical trials and meta-analysis of clinical trials (excluding BART) did not show an association between aprotinin and perioperative mortality. Aprotinin now has a tighter licence in place, additional recommendations on heparin monitoring, renal impairment and anaphylaxis. Also, all use must be recorded with the manufacturer's registry to audit usage. The committee agreed that it was safe to restart aprotinin use for its licensed indication only. It was agreed that use would be reviewed in six months. **Semaglutide – Dr K Mohammed & Endocrinology Team** The committee reviewed the evidence presented with the application for this weekly GLP-1 receptor agonist. Approved for addition to the formulary. **Tofacitinib for ulcerative colitis– Prof S Sebastian** Application made in line with NICE TA547. Committee approved for use. **Hydrocortisone granules in capsules for opening (Alkindi) – Line extension –Paediatric Endocrinology Team** Approved as a licensed product suitable for children, in strengths 0.5, 1, 2 & 5mg. To replace off label buccal tablet use and unlicensed liquid, where the granule formulation was suitable for the dosage required.	Approved for licensed use only. POB to implement manufacturer registry scheme. Approved. Approved. Approved.	AM to write to applicant and state that approval is for licensed use only POB to discuss registry requirements with YH and clinical team AM to write to applicants and WH to update formulary for all SG to request AR to update gastro biological pathway	AM POB AM WH SG	4/19 4/19 4/19 4/19 4/19	
2019.03.06	**NICE Guidance**	**NICE Guidance – February 2019** NG120 Cough (acute): antimicrobial prescribing	Noted. All antibiotics on formulary.	No further action			3/19

		TA560 Bevacizumab with carboplatin, gemcitabine and paclitaxel for treating the first recurrence of platinum-sensitive advanced ovarian cancer (terminated appraisal)	Noted.	No further action			3/19
		TA561 Venetoclax with rituximab for previously treated chronic lymphocytic leukaemia	Both on formulary.	No further action			3/19
		TA562 Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma	Both non-formulary. Application to be requested.	WH to request ARIA application		4/19	
		TA563 Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer	Abemaciclib non-formulary. Application to be requested.	WH to request ARIA application		4/19	
		TA564 Dabrafenib with trametinib for treating advanced metastatic BRAF V600E mutation-positive non-small-cell lung cancer (terminated appraisal)	Noted.	No further action			3/19
		CG62 Antenatal care for uncomplicated pregnancies	Noted.	No further action			3/19
2019.03.07	**Free of Charge (FOC) Medicines Schemes - V 1.0, RMOC, July 2018**	This paper was on the agenda again for discussion, as it is felt that the document is open to interpretation. The Trust D&T Committee always reviews new medicine requests on a clinical efficacy and safety basis, in line with the terms of reference, based on NICE MPG1: Developing and updating local formularies. Decisions are never based solely on cost. The committee wanted to confirm that the purpose of this document is not to instantly dismiss the use of FOC medicines. The committee felt that there are areas where clarity is lacking e.g. 1.3 “Trusts or commissioners should not sign up to a FOC scheme which is solely offering a licensed medicine free of charge in advance of NICE approval“ The document also states in section 7.8 that “Any potential financial risk to the commissioner must be agreed with the commissioner prior to FOC scheme being started.” It was felt that the committee should write to seek clarification around these points.	POB to write to the named authors on the RMOC FOC document.	POB to write to RMOC	POB	4/19	

2019.03.08	**MHRA Drug Safety Update**	**February 2019** Carbimazole increased risk of congenital malformations; strengthened advice on contraception The Trust Thyroid Disorders in Pregnancy guideline includes carbimazole. It was thought helpful to write to Prof Sathyapalan (Endocrinology) & the guideline authors (Gynaecology) - Mr Boakye & Miss Hingorani. Carbimazole increased risk of acute pancreatitis SGLT2 inhibitors: reports of Fournier's gangrene	Write to Endocrinology & Gynaecology to make them aware. Noted. Noted.	AM to write to the appropriate consultants	AM	4/19	
2019.03.09	**Minutes from SMPC**	November 2018	Noted.				3/19
2019.03.10	**Minutes from HERPC**	November 2018	Noted.				3/19
2019.03.11	**Regional Medicines Optimisation Committees**	• 22/01/19 Regional Medicines Optimisation Committees - North Update - November 2018 • 11/02/19 Maintaining Patency of Central Venous Catheters in Adults: RMOC Position Statement - February 2018 • 21/02/19 Medicines Governance Do Once Programme • 19/02/19 Private Recording of MUS Monthly Webinar: An overview of the current RMOC work plan - 13 February 2019	Noted.				3/19
2019.03.12	**Correspondence received**	**Emerade adrenaline pen line extension - Dr P Gordins** Dr Gordins had written requesting that a second adrenaline pen was made available, given the recent supply issues with EpiPen. This line extension was also requested as Emerade is available in a 500microgram dose and the device is easy to use and has a long needle. The committee felt it was best to have Emerade in addition to EpiPen, as many patients were already established and well controlled on EpiPen. Any patients who were changed over would need appropriate training, to ensure safe use. **Cannabidiol (Epidiolex) – Dr S Jose** E-mail received from Dr Jose, informing the committee of the positive improvement seen in the patient receiving Epidiolex. There had been a 70% reduction in seizures and the family had e-mailed to say they were very grateful to have had access to	Emerade approved. The committee noted the positive feedback.	AM to write to Dr Gordins WH to update formulary	AM WH	4/19 4/19	3/19

		the drug through the compassionate use scheme, via the Leeds specialist centre. **Procurement of Direct Acting Oral Anticoagulants (DOACs) letter – Dr P Reading, NLAG Chief Executive - 19.2.19** DC had received this letter from NLAG, regarding the potential of cost savings in primary care, if one main DOAC is used for AF. NLAG and the Cardiology network were looking at this, but had paused the process to include other Trusts & CCGs in the Humber, Coast and Vale STP area. Currently there are four DOACs available on the Trust/joint formulary, with NICE TAs for this condition. Edoxaban was the DOAC used preferentially in the Tayside switch scheme. Dosing was simpler than some DOACs, with 60 or 30mg daily doses, based on weight, renal function and some interactions. The committee agreed that we should be involved in the process and liaise with relevant colleagues to seek their views. **Dalbavancin for Osteomyelitis - Lorraine Cullen** SG had received an email, requesting the use of dalbavancin in osteomyelitis following publication of an article in the Open Forum Infectious diseases journal: https://academic.oup.com/ofid/article/6/1/ofy331/5235615. The dose would be 1.5g IV on day 1 followed by a further dose of 1.5 g on day 8. The original application was for the licensed single dose of 1.5g on day 1. The e-mail stated that dalbavancin will only be considered when patients have at least 4 weeks of antibiotic therapy remaining (most likely 6-8 weeks) to avoid prolonged courses with other agents. In this situation dalbavancin (£4020 incl VAT) would be more cost effective than 4 weeks tedizolid (£4023 excl VAT via Boots). If less than 4 weeks course was required, tedizolid would be more cost effective. It was thought usage may be 18-24 per year in this patient group.	DC will discuss further with NLAG chief pharmacist. SG will raise at next Thrombosis Committee on 5/4/19, including Stroke specialists and feed back. Approved clinically, based on the published trial data.	DC to feedback next time SG will feed back next time AS will raise at ACAT and ID business meeting to discuss costs and how best to target correct usage.	DC SG AS	4/19 4/19 4/19	
2019.03.13	**Chairs approvals**	None this month.					3/19
2019.03 14	**Issues to escalate to OQC**	No issues to escalate this month. DC informed the committee that erenumab should have been discussed at OQC, but the committee had not sat for some time due to pressures on the trust. Despite this, erenumab and the	Noted.	No further action			3/19

		manufacturer's FOC scheme had been discussed at Trust executive/board level and with CCG colleagues. The current outcome was that we would not start using the drug, but await the NICE TA guidance.					
2019.03.15	**Any Other Business**	AS informed the committee that ACAT meetings would be starting again, with a revised format. It was the intention to hold the meetings more frequently than the previous four times a year, with wider representation from health group colleagues.	Noted.	No further action			3/19
2019.03.16	**Date and Time of Next Meeting**	**Date:** Thursday 11th April 2019 **Time:** 8.15-9.30 **Venue:** Meeting Room 3, Women's & Children's Hospital					