EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST

NEW DRUG AND INTERFACE GROUP

MINUTES OF THE MEETING HELD ON WEDNESDAY 13th APRIL 2016
IN PINK ROOM, GROUND FLOOR, B BLOCK, ST HELIER HOSPITAL

Present:
Dr S Patel (Chair) **SP**
Dr V De Silva (Consultant Nephrologist) **VDS**
Dr S Moodie (Consultant Gastroenterologist) **SM**
Dr S Rahman (Consultant in Respiratory Medicine) **SR**
Dr P O'Mahony (Consultant Stroke Physician) **PO**
Anne Davies (Chief Pharmacist) **AD**
Sharon Kitcatt (Consultant Nurse – Acute Pain Service) **SK**
Sarah Taylor (Chief Pharmacist, Sutton CCG) **ST**
Liz Clark (Lead Commissioning Pharmacist, Surrey Downs CCG) **LC**
Dr R Scott (Joint Medicines Management Lead – GP Sutton CCG) **RS**
Anne Lowson (Secretary) **AL**

In attendance:
Sumbo Adeyemo (Medicines Management Pharmacist) **SA**
Vanya Slavova Boneva (Medicines Management Pharmacist) **VSB**
Susie Fogg (Administration Coordinator) **SF**
Sabrina Hasan (Pre-registration Pharmacist) **SH**
Dr A Bansal (Consultant Immunologist) **AB**
Mr P Athanasias (Consultant Gynaecologist) **PA**
Dr V Varney (Consultant in Respiratory Medicine) **VV**

No	Item	Responsible for Action
1.	**Apologies for Absence** Dr J Bendig (Consultant Microbiologist) **JB** Susie Mallinder (Lead Renal Nurse) **SM** Dr A Pitsiaeli (GP, Surrey Downs CCG) **AP** Michelle Barnard (Principal Pharmacy Technician) **MB**	
2.	**Declarations of Interest** Nil declared for this meeting.	
3.	**Terms of Reference – Revised** The terms of reference have been amended in line with comments received. Reference to the non-medical prescribing committee removed and reporting/accountability has been amended to reflect current Trust structure. Final versions to be added to Trust intranet.	**SF**
4.	**Minutes of the Meeting held on the 10th February 2016** Minutes were agreed.	
5.	**Matters Arising**	
a)	**Ranibizumab Switching Policy** Work ongoing with Mr Saeed on finalising this document.	**AD**
b)	**SWL - Pathway for Melatonin** Work ongoing with Sutton CCG to finalise this document.	**AL/ST**
c)	**6 mercaptopurine and azathioprine for IBD shared care**	

	Sutton CCG has supported this proposal. Awaiting decision by other SWL CCG's. Update at next meeting. Final version to be brought back to a future meeting.	**AD/ST**
6.	**New Drug Requests**	
a)	**Vitamin B12 for Chronic Fatigue Syndrome (Amdpharm)** Dr Bansal presented the case for using vitamin B12 injections to help improve the symptoms of Chronic Fatigue Syndrome (CFS) and Myalgic Encephalopathy (ME). The prevalence rate for these conditions is increasing and it is a disease which is difficult to treat and with no cure. NICE guidance has been published but the pharmacological interventions are few e.g. tricyclics and the evidence for these is still weak. NICE guidance does not support the use of vitamin B12 in these conditions. Vitamin B12 is recognised in use for normal haematopoiesis and in normal nerve conduction. The precise mechanism of action of vitamin B12 relates to its importance as a methyl donor in DNA synthesis and in preventing accumulation of homocysteine. Other studies have shown it has ability to promote nerve injury repair and anti-inflammatory and anti-oxidant actions. Viral infections have been considered as aetiological agents of CFS/ME and vitamin B12 may have anti-viral activity. CFS is characterised by prolonged severe fatigue and small studies have shown that vitamin B12 has beneficial effects by improving physical and mental stamina and reducing the perception of fatigue. The studies however do not have measurements of the response and are not placebo controlled. The proposed dosage of vitamin B12 injection is higher than detailed in the BNF and baseline levels are not measured. The plan is to achieve super physiological levels. If it is found to be helpful after 10 weeks then patients are given the option to continue treatment. It is not licensed for use in these doses and the long term side effects not known. Dr Bansal advised that there are no published studies showing harm. Higher doses are given for other indications but treatment is shorter term. Dr Bansal has been using the injections for 7 years and recently sought the views of 42 patients who had received treatment. Approximately half perceived that vitamin B12 therapy significantly improved their physical fatigue and a smaller number 19/41 found it helped mental fatigue. It was felt by a third of patients that it had allowed them to continue to work. The committee did discuss the placebo effect and that it could explain some or all of the benefit. Other centres in Newcastle, Leeds and the Royal Free in London have been using vitamin B12 in this patient cohort. It was also recognised that vitamin B12 was used for other indications e.g. Crohn's disease and as part of cancer treatment to relieve fatigue. Dr Bansal advised that he was planning a clinical trial and currently sourcing placebo injections to allow a double blind RCT to be completed. **Decision** The committee agreed that the evidence base was weak, long term safety was unknown and the treatment of CFS and ME with vitamin B12 was not currently supported by NICE. The request to use it in the Trust or to recommend GP's prescribe vitamin B12 in this patient cohort was rejected. However it was recognised that a trial would be useful in strengthening the evidence base. Dr Moodie did not support this decision and requested this be minuted.	**SP**
b)	**Ulipristal for Uterine Fibroids (Gedeon Richter)** Mr Athanasias presented the case for extending the indication for use of ulipristal on the Trust formulary following a licence extension by the	

	manufacturer. Ulipristal is now indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, making it the only licensed oral product for long term medical management of symptomatic fibroids. This could help significantly reduce the number of women who have to have surgery or radiological interventions for this disease. The evidence shows that fibroids shrink progressively from each additional course of treatment (up to four courses). There is likely to be a longer gap between courses as treatment progresses and it would be started after menstrual bleed for a period of 3 months. The main patient who would benefit are peri-menopausal women and those women not fit for surgery. Patient numbers are small at approximately 25 per site. GP's felt it would be useful to be informed about what side effects these patients would expect and what to do if there was irregular bleeding. Mr Athanasias advised patients should receive another scan in hospital if there was irregular bleeding and that this would be detailed in the clinic letter. The possibility of shared care was discussed but it was felt that GP's would need greater experience and support to manage these patients. Surrey PCN will discuss shared care for their GP's at the next PCN as part of the new drug request. **Decision** To agree to the use of ulipristal for intermittent treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age. GP's to be informed in clinic letters of when to refer patients back to hospital e.g. if irregular bleeding. The drug will remain hospital only until the possibility of shared care has been reviewed by CCG's.	**AL**
c)	**Umeclidinium Incruse Ellipta® for COPD (GlaxoSmithKline UK)** Dr Varney presented the case for the addition of umeclidinium for management of COPD to the Trust formulary. It is a LAMA in a dry powder inhaler and the Respiratory Working Group support this application. There is a clear place in therapy for LAMA inhalers in national guidance (NICE CG101 and GOLD COPD 2016). Evidence is from 2 phase III RCT's comparing it with placebo. No comparative studies with other LAMA's or LABA's have been performed. Long term safety data is not yet available for the licensed dose. It is presented in a new type of device which has been designed to be easy to use and is administered once daily. The manufacturer has developed a LAMA, LAMA/LABA and ICS/LABA in the same device and therefore if the patient prefers this device they will be able to progress to dual or triple therapy without changing device. Once in use the inhaler has a 6 week expiry. The cost is comparable to the other newer LAMA e.g. glycopyrronium and cheaper than tiotropium. The committee did recognise that tiotropium does have more long term evidence and safety data so some clinicians will be reluctant to switch patients treatment. **Decision** To add umeclidinium bromide inhaler (Incruse®) to the Trust formulary for maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. To be added to the Trust poster of inhaled therapies for COPD together with a statement around device choice. The choice of device is based on patients ability to use the device, patient preference and cost effectiveness.	**SA**

7.	**Six Month New Drug Reviews** Nothing for this meeting.	
8.	**NICE Guidance**	
	Updates	
a)	**Vortioxetine for treating major depressive episodes – TA367** The Chief Pharmacist for South West London and St George's Mental Health Trust has advised that they feel the place in therapy is small and it is likely to be initiated by mental health specialists. The Trust will therefore add vortioxetine to the formulary expecting it to be used for patients admitted on therapy only.	**AL**
b)	**Revised Dry Eye Protocol- Incorporating NICE TA369** This document was revised to incorporate the newly licensed strength of ciclosporin eye drops 0.1%. The 0.05% will remain available for patients unable to tolerate the higher strength but as this is unlicensed, supplies will be hospital only. Document agreed.	**AL**
c)	**Nintedanib for treating idiopathic pulmonary fibrosis – TA379** Nintedanib is funded via NHSE but clarity is required over whether this would be initiated by a tertiary centre. Diagnostic work for idiopathic pulmonary fibrosis is carried out at Epsom and St Helier.	**AL**
d)	**Intravenous fluid therapy in children and young people in hospital – NG29** Comments received from Dr Kilonback and Dr Hadley. This guidance reflects current practice to use isotonic fluids. 0.18% sodium chloride was previously removed from the paediatric wards. It was not felt necessary to add 0.45% sodium chloride with 2.5% glucose to the formulary. A ready-made 2.7% sodium chloride is available on formulary and used mainly for managing raised intracranial pressure.	
e)	**Tuberculosis – NG33** Feedback from Dr Kahr once the minutes from the Trust meeting are available.	
	Technology Appraisals for Discussion	
f)	**Nivolumab for treating advanced (unresectable or metastatic) melanoma – TA384** The Trust do not treat advanced melanoma and will therefore add nivolumab to the formulary for use in patients admitted on therapy.	**AL**
g)	**Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia - TA385** Comments received from Dr Johri and Dr Wilcox advise that current practice is in line with the recommendations and no significant change in practice is expected. Ezetimibe to remain on formulary.	
h)	**Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis – TA386** Dr Zuha has advised that this guidance is in line with current practice and currently have 3-5 patients a year on treatment.	
	Technology Appraisals for Information	
i)	**Updated guidance on the use of temozolomide for treatment of recurrent malignant glioma- TA23** This is a rewording of the recommendation in line with NICE's wording conventions.	
	Clinical Guidelines for Discussion	
j)	**Myeloma: diagnosis and management – NG35** Dr Zuha has advised that they have reviewed their practice in line with this guidance. They will consider whole body MRI or whole body low dose CT as first	

	line imaging and testing of all patients for hepatitis B/C and HIV prior to treatment for myeloma. No pharmacological issues require addressing.	
k)	**Fractures (non-complex): assessment and management – NG38** The drugs listed for pain management are on the Trust formulary. Dr Benkaifer has advised the Trust do not currently perform fascia iliaca blocks in children, only adults when levobupivacaine 0.25% is used as per formulary.	
l)	**Major trauma: assessment and initial management – NG39** Patients would be treated at other centres for major trauma but the Trust currently have the medicines on formulary. Dr Benkaifer has advised they will be reviewing the need for intranasal ketamine and intranasal diamorphine in adults in the future.	**AL**
m)	**Spinal injury: assessment and initial management – NG41** The drugs listed for pain management are on the Trust formulary.	
n)	**Motor neurone disease: assessment and management – NG42** Dr Lovelock has advised that Botox® is not offered for sialorrhoea and that carbocisteine should be available in the Trust for prescribing by neurologists. This will be reflected in the formulary status.	**AL**
	Clinical Guidelines for Information	
o)	**Sunlight exposure: risks and benefits – NG34** For information.	
p)	**Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over – NG36** For information.	
q)	**Fractures (complex): assessment and management – NG37** For information.	
r)	**Transition from children's to adults' services for young people using health or social care services - NG43** For information.	
s)	**Updated- Diabetic foot problems: prevention and management – NG19** For information.	
t)	**Updated- Attention deficit hyperactivity disorder: diagnosis and management – CG72** For information.	
u)	**Updated- Epilepsies: diagnosis and management - CG137** For information.	
v)	**Updated- Bipolar disorder: assessment and management – CG185** For information.	
w)	**Updated- Antenatal care for uncomplicated pregnancies- CG62** For information.	
	Diagnostics Guidance for Discussion	
x)	**Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system) – DG21** The MiniMed Paradigm Veo system would be used within the Trust in accordance with NICE however concern has been raised regarding the service provision for implementation. Funding will be allocated by CCG's via Blueteq for adult patients. A business case is in development to support paediatric CGMS use.	
	Diagnostics Guidance (Not recommended)	
y)	**Therapeutic monitoring of TNF-alpha inhibitors in Crohn's disease**	

	(LISATRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits) - DG22 Not recommended.	
	MHRA Guidance	
z) **aa)**	**February 2016** **March 2016** Trust clinicians have been advised of these updates.	
	Patient Safety Alert	
bb)	**Risk of severe harm or death when desmopressin is omitted or delayed in patients with cranial diabetes insipidus** This PSA has been circulated via e-update to all Trust staff. Following discussion with Dr Hyer, it was recognised clinicians, pharmacists and nurses need to be aware of this PSA which advises the urgency of treatment to avoid patients with diabetes insipidus becoming seriously dehydrated. The desmopressin nasal spray has been placed in the emergency cupboards on both sites and the injection is already available in intensive care areas.	
9.	**Operational Issues**	
a)	**NSTE-ACS Risk Stratification and Management Guideline** This document has been prepared by the cardiologists and shared at this meeting to advise on the place in therapy of ticagrelor in the management of NSTE-ACS. Comment requested from CCG's on this document. Dr Patel advised that currently the Trust are reviewing all statements on guidance relating to the use of eGFR for drug dosing and the document will be reviewed in line with the outcome of these discussions.	**SP/LC/ST/AL**
10.	**Feedback from CCGs and Trust Committees**	
a)	**<u>Respiratory Working Group</u>** Nothing for this meeting.	
b)	**<u>NOAC's</u>** **I. Update on treatment for DVT and PE with NOAC's** This work is moving forward as the Trust have received agreement from the commissioners to use DOAC's as a treatment option.	**SP/AD/AL**
c)	**<u>SWL Sutton & Merton CCG's</u>** **I. Minutes – January 2016** For information.	
d)	**<u>Surrey Prescribing Clinical Network</u>** **I. Minutes – February 2016** **II. Minutes – March 2016** Minutes for information. **III. Toujeo (insulin glargine 300units/ml) in type I diabetes** **IV. Toujeo (insulin glargine 300units/ml) in type II diabetes** The Trust have an outstanding application for Toujeo® which will be discussed at a future NDAIG meeting. The issues relating to the prescribing of a different strength of insulin (330units/ml than 100units/ml) will be discussed then. **V. Xultophy (insulin degludec/liraglutide) in type II diabetes** The Trust have already agreed a place in therapy for Xultophy®. Initiation will be by consultant endocrinologists only and supplies will be issued by the hospital. Concern was expressed by the committee that Surrey PCN have classified this as black on their traffic light system. **VI. Dose extension protocol – Biologic use in Rheumatology patients** The Trust rheumatologists support this dose extension protocol. **VII. Vortioxetine for treating major depressive episodes**	

	The Trust support this PCN policy statement (see 8a also). **VIII. Omalizumab for previously treated chronic spontaneous urticaria** The Trust support this PCN policy statement. **IX. Liothyronine (T3) for patients post thyroidectomy** The Trust support this PCN policy statement. **X. Biosimilar Etanercept (Benepali®) use for all licensed indications in adults** The Trust are starting all new patients on biosimilar etanercept and switching patients as and when appropriate. Communication to Trust clinicians before the Blueteq forms were changed to allow biosimilar preparation only would have been helpful as internal processes, supporting documentation and education need to be put in place. **XI. Liothyronine (T3) for the treatment of coma of myxedema** The Trust support this PCN policy statement. **XII. Liothyronine (T3) for the treatment of thyrotoxicosis** The Trust support this PCN policy statement. **XIII. Thyroid extracts, liothyronine (L-T3) monotherapy, compound thyroid hormones, iodine containing preparations and dietary supplementation in the management of Hypothyroidism** The Trust support this statement however the issue related to liothyronine monotherapy in patients with thyroxine intolerance remains to be addressed. **XIV. Triptans for migraine or cluster headaches** The Trust have a range of triptans for management of migraine or cluster headaches but it does not have all these preparations on the formulary. **XV. Dulaglutide (Trulicity®) (GLP-1) for improving glycaemic control in adult patients with Type II Diabetes** The Trust have not reviewed this preparation for addition to the formulary but will consider this statement policy if it receives a request. **XVI. Liothyronine (T3) for the treatment of resistant depression in adults** The Trust are not currently using liothyronine for resistant depression. **XVII. Ciclosporin (Ikervis®) eye drops for the treatment of dry eye disease that has not improved despite treatment with artificial tears (INTERIM)** The Trust have added this strength of ciclosporin eye drop to the formulary and it is included in the dry eye protocol. The information sheet will be circulated to Trust clinicians once available.	
e)	**<u>Shared Care Prescribing Guidelines</u>** Nothing for this meeting.	
11.	**Any Other Business** The committee expressed its thanks to Michelle Barnard for her help and support to the committee over the last few years. It wishes her well in her future role in the Trust.	
12.	**Date of Next Meeting:** Wednesday 15th June 2016, 12.30-2.00pm, Boardroom, Ground Floor, Rowan House, Epsom Hospital.	