EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST

NEW DRUG AND INTERFACE GROUP

MINUTES OF THE MEETING HELD ON WEDNESDAY 15th JUNE 2016
IN BOARDROOM, GROUND FLOOR, ROWAN HOUSE, EPSOM HOSPITAL

Present:
Dr S Patel (Chair) **SP**
Dr V De Silva (Consultant Nephrologist) **VDS**
Dr R Shephard (Consultant Neonatologist) **RS**
Dr M Gardner (Consultant Anaesthetist) **MG**
Dr L Mulleaue (Consultant Anaesthetist) **LM**
Anne Davies (Chief Pharmacist) **AD**
Liz Clark (Lead Commissioning Pharmacist, Surrey Downs CCG) **LC**
Prem Bhalla (Senior Primary Care Pharmacist, Sutton CCG) **PB**
Anne Lowson (Secretary) **AL**

In attendance:
Sumbo Adeyemo (Medicines Management Pharmacist) **SA**
Susie Strange (Administration Coordinator) **SS**
Abisola Ojo (Rotational Pharmacist) **AO**
Dr R Nithyananthan (Consultant Diabetologist) **RN**
Dr J Ratoff (Consultant in Respiratory Medicine) **JR**

No	Item	Responsible for Action
1.	**Apologies for Absence** Dr J Bendig (Consultant Microbiologist) **JB** Dr P O'Mahony (Consultant Stroke Physician) **PO** Dr R Bogle (Consultant Cardiologist) **RB** Susie Mallinder (Lead Renal Nurse) **SM** Sharon Kitcatt (Consultant Nurse – Acute Pain Service) **SK** Dr R Scott (Joint Medicines Management Lead – GP Sutton CCG) **RS** Sarah Taylor (Chief Pharmacist, Sutton CCG) **ST** Vanya Slavova Boneva (Medicines Management Pharmacist) **VSB**	
2.	**Declarations of Interest** Nil declared for this meeting. Dr Nithyananthan advised the manufacturers of insulin had sponsored a diabetes masterclass for the Trust but no personal conflict of interest.	
3.	**Minutes of the Meeting held on the 13th April 2016** Minutes were agreed. LC reminded the committee that a letter to GP's from Dr Bansal also requested GP's consider prescribing other medications not currently supported by NICE. SP to follow up.	**SP**
4.	**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. Links with the SWL Mental Health Trust have been made.	**ST/AL**
5.	**New Drug Requests**	

a)	**Testosterone Gel 1% for Hypogonadism** Dr Nithyananthan presented the case for Testim® gel for testosterone replacement therapy for male hypogonadism when testosterone deficiency has been proved by clinical features and biochemical tests. The SMC has accepted its use when a patient requires a transdermal delivery system advising it is at least as effective as testosterone patches and costs less. Small studies have shown AUCO_24 and Cmax for total testosterone were consistently higher following application of Testim® compared to the current formulary option Testogel®. The enhanced absorption may be due to the increased emollient qualities. Dr Nithyananthan advised the main reasons for the request related to patient benefits. The volume of gel may be smaller making application easier and therefore adherence to therapy better. There is also a lower application site reaction rate with Testim® (4% v's 10% for patients on Testogel®). Cost difference is very small. A minority of patients require the 100mg strength. Testim® could replace Testogel® as Dr Nithyananthan advised the endocrinologists at St Helier supported this switch. GP's could be asked to carry on management of these patients once the patient's treatment is stable. Sutton and Merton supported a review in 6 months' time but clear criteria to be identified and brought back to the next meeting. **Decision** To add Testim® (testosterone gel 1%) to the formulary and remove Testogel®. Once a patients therapy is stable GP's may be asked to prescribe in line with current practice for testosterone gel. Tostran gel® to remain on the formulary as it is used in menopausal women in accordance with NICE guidance NG23. **Post Meeting:** Directorate funding agreement only as 2nd line to Testogel®.	**SA**
b)	**Insulin Glargine Abasagler® 100units/ml biosimilar** This is a basal insulin for once daily use and NICE have advised it is non-inferior to insulin glargine (Lantus®) in patients with Type 1 and Type 2 diabetes and have also advised the safety profile of Abasagler® is comparable to Lantus®. Biosimilars have the potential to offer the NHS considerable cost savings. The original request came from Dr Rodin but Dr Nithyananthan presented the case on behalf of the Trust diabetologists. It is available as cartridges of 100units/ml for use in a reusable pen and as a prefilled pen of 100units/ml. NICE guidelines have a clear place in therapy for NPH (isophane) insulin and the long acting insulin analogues e.g. insulin glargine, insulin detemir or insulin degludec in NG17 (type 1 diabetes) and NG28 (type 2 diabetes) and the Trust are currently following this guidance. The place in therapy of Abasaglar® would be the same as other insulin analogues. The cost of Abasagler® is currently cheaper than Lantus® both in primary and secondary care. With regards to switching patients from one preparation to another a small subgroup was switched from Lantus® to Abasagler® at the same dose regimen in the phase III clinical studies and no difference in dose changes after titration to tighten glucose blood control was reported between the 2 treatment arms. The MHRA have advised that some dose adjustment may be needed for some patients and therefore a switch programme would need to be devised which would include suitable patient groups, dose switching protocols and monitoring. The Trust do not plan to switch patients at present. Other recommendations for safety would be brand prescribing and ensuring patients have an Insulin Passport or equivalent.	

	Decision To add Abasagler® to the Trust formulary as a treatment option for patients with type 1 and 2 diabetes where an insulin analogue is indicated in line with NICE guidelines. New patients requiring insulin glargine will be started on Abasagler® but patients will not currently be switched from Lantus® to Abasagler® in the Trust. Primary care are following a similar approach. **Insulin Glargine Toujeo® 300units/ml** This preparation has been developed for people with type 1 or type 2 diabetes who have large daily insulin requirements to reduce the number and volume of injections. Trials have shown it has similar efficacy to Lantus® in terms of HbA1c reduction. There was a statistically significant reduction in confirmed or severe nocturnal hypoglycaemia with Toujeo® in 2 of the RCT's but not the 3rd. NICE have advised the safety profile of Toujeo® is largely similar to that of Lantus®. Dr Nithyananthan advised that as a lower volume of insulin is needed to give the same dose it is better absorbed meaning that Toujeo® is not bioequivalent to Lantus® and not interchangeable without dose adjustment. Toujeo® is given once daily preferably at the same time each day but can be given up to 3 hours before or after the usual time. To minimise the risks of having a higher strength preparation which is not bioequivalent: • The manufacturers have only prepared Toujeo® in a pen device. The number of units are dialled in. No dose re-calculation is required for the strength. • A guide for patients and carers devised as well as one for healthcare professionals. • Switching protocols are included in the product literature. The MHRA advises brand prescribing, patients have insulin passport or equivalent provided. Internally there needs to be a risk assessment of Toujeo® with regards to picking errors and storage in the fridges in wards and pharmacy, ePMA prescribing, education for all general staff around not switching/using an alternative brand for dosing if one product is not available. **Decision** To add Toujeo® to the Trust formulary as a treatment option for patients with type 1 and type 2 diabetes where insulin glargine is indicated in line with NICE guidelines (NG17 type 1) (NG28 type 2). Initiation should be by consultant diabetologist or a clinician with specialist interest in diabetes in patients: • Where attempts to achieve HbA1c levels with multiple injections result in hypoglycaemia or high fasting blood glucose. • Those patients on twice daily basal insulin receiving a large volume of injections of Lantus® causing pain and/or poor absorption. • Patients who are dependent on others to administer their insulin as Toujeo® is given within a 3 hour window. Risk assessment to be carried out prior to starting the prescribing of Toujeo® in the Trust. The PCN have supported the use of Toujeo® and have a detailed place in therapy. Discussed at the last meeting.	**VSB**
c)	**Spiolto® Inhaler for COPD** Dr Ratoff presented the case for the addition of Spiolto Respimat® (tiotropium and olodaterol) soft mist Inhaler to the formulary for management of COPD. It	

	is an alternative LABA/LAMA preparation and the place in therapy of these agents has been agreed previously by this committee. The advantages over the other LABA/LAMA combinations on the formulary is that it is the only MDI and requires a low inspiratory flow rate. Some patients like the fact that they can see and feel the mist which confirms the device is working. One disadvantage is that although it is an MDI it is not licensed for use with a spacer. The cost is similar to the other dry powder LABA/LAMA devices on formulary. They all cost less than combination treatment with two individual component inhalers. There are no trials currently comparing the LABA/LAMA preparations. NICE advise that choice of drug should take into account patients response and preference, drugs potential to reduce exacerbations, its side effects and cost. NICE have recently reviewed the evidence for Spiolto Respimat® and this was presented to the committee. It was discussed that the device needs priming if it has not been used for more than 7 days and in a different way if not used for more than 21 days. However patient education was felt to be key in minimising problems with this, and ensuring patients were using it once daily as prescribed. **Decision** To add Spiolto Respimat® (tiotropium and olodaterol) to the formulary for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).	**SA**
	For Information	
d)	**Idarucizumab Praxbind®** For information the Trust will be adding idarucizumab to the formulary for reversal of dabigatran in moderate/severe bleeding or life threatening bleeding and/or need for emergency surgery. A draft protocol for reversing DOAC's was presented. Once a location for storage has been agreed internally the document will be circulated and staff made aware of the process for obtaining it.	**AL**
e)	**Fortisip Compact Protein®** Fortisip Compact Protein® will now become the Trusts first line nutritional supplement for adult patients as most patients will benefit from the additional protein when compared to that in Fortisip Compact. Primary care expressed concern that if the patient is discharged on the Fortisip products either compact or protein patient expectation is they should also receive this from their GP. There were suitable alternatives and these were being promoted in primary care due to the cost. This switch is cost neutral in the Trust and cheaper in secondary care than primary care. The dietitians are aware of this and have been asked to inform patients that alternatives may be prescribed. Pharmacists will also be reminded that nutritional supplements should only be supplied on discharge if patients have had dietitian input and they have advised it should be continued on discharge.	**SA/AL**
f)	**Aprepitant for CINV** Antiemetic guidelines for adults receiving chemotherapy and radiotherapy have been devised by the London Cancer New Drugs Group. Aprepitant is included for use in certain highly emetogenic chemotherapy regimens. It is an NK-1 receptor antagonist. When used in combination with corticosteroids the dose of steroid should be reduced. Aprepitant capsules will be added to the Trust formulary in line with this guidance.	**AL**
g)	**Argatroban for Heparin induced thrombocytopenia** The Trust have revised their anticoagulation protocol for heparin induced	

	thrombocytopenia (HIT) in adults. Danaparoid is licensed for treatment of HIT but currently rarely available and alternatives are needed. Fondaparinux is not licensed so usage is off label but the BJH recommendations support its use (document circulated to committee). Argatroban is licensed but is complicated to administer (mcg/kg/min) and requires APTT monitoring. For safety reasons it has therefore been restricted to use where there is thrombosis and high bleeding risk or thrombosis present and CrCl < 50ml/min or patient on renal replacement therapy. Prescribing guidelines have been devised to minimise the risk of use with argatroban. Argatroban will be added to the Trust formulary as hospital only in line with this guidance.	
6.	**Six Month New Drug Reviews** Nothing for this meeting.	
7.	**NICE Guidance**	
	Updates	
a)	**Nintedanib for treating idiopathic pulmonary fibrosis – TA379** Dr Ratoff advised that the respiratory clinicians were aware of this NICE TA and there would be Trust patients who would be eligible for treatment. At present these patients would be referred to a tertiary service for review and initiation. Funding is via NHSE via specialist centres. Nintedanib will be added to the formulary in line with the TA379.	
b)	**Tuberculosis – NG33** Dr Kahr has provided the minutes from the TB MDT meeting in March 2016. These highlight a number of changes which may impact on current practice, workload and have a financial implication for the Trust. This will be considered by the division. There are no changes to the formulary following the release of this guidance.	
	Technology Appraisals for Discussion	
c)	**Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated – TA387** Abiraterone will be added to the Trust formulary in line with this NICE TA, however as these patients would not be initiated on treatment by the Trust it will only be available for patients admitted to the Trust already on treatment.	**AL**
d)	**Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction – TA388** Sacubitril valsartan (Entresto®) is an angiotensin receptor neprilysin inhibitor. It is licensed for and approved by NICE for the treatment of symptomatic chronic heart failure with reduced ejection fraction. It should be started by a heart failure specialist with access to a multidisciplinary heart failure team and dose titration and monitoring will be done by this team. SWL Cardiac and Stroke Network have produced draft prescribing guidance and screening checklist and notification of initiation to GP and a transfer of prescribing responsibility forms. Trust clinicians have expressed concern that the forms are additional administration and many drugs for managing heart failure require dose titration and monitoring and GP's do this without this documentation. However this was felt to be appropriate for this new therapeutic class. Once the patient is on maximum tolerated therapy the patient can be transferred back to the GP. The final versions of these documents will be uploaded onto the Trust intranet once available and the same process will be followed for Surrey CCG patients. Entresto® will be added to the Trust formulary in line with this NICE TA.	**AL**
e)	**Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer – TA389** Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel,	

	trabectedin and gemcitabine will be added to the Trust formulary in line with this NICE TA however as these patients would not be initiated on treatment by the Trust they will only be available for patients admitted to the Trust already on treatment.	**AL**
f)	**Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes – TA390** The diabetologists have been made aware of this NICE TA but no response received. The drugs are already available on the Trust formulary and will remain available for use in line with this NICE TA. The committee also noted that they can slow down the rate of decline in renal function.	
g)	**Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel – TA391** Cabazitaxel will be added to the Trust formulary in line with this NICE TA however as these patients would not be initiated on treatment by the Trust they will only be available for patients admitted to the Trust already on treatment.	
h)	**Updated - Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease – TA217** Currently both Surrey Downs and Sutton CCG's require patients to be referred to the mental health Trusts for initiation. GP's then maintain prescribing in line with the NICE guidance. However certain Trust specialists e.g. geriatricians and neurologists, (in the case of PD dementia of Lewy Body) would like to be able to initiate in certain patients. CCG representatives will seek current views on commissioning.	
	Clinical Guidelines for Discussion	
i)	**Controlled drugs: safe use and management – NG46** A gap analysis has been prepared and this will be discussed at the next MMCBG in July. Following the review will be shared with the CD Trust Accountable Officer (Chief Nurse).	
j)	**Updated - Psychosis and schizophrenia in children and young people: recognition and management – CG155** The Trust do not currently initiate treatment for psychosis and schizophrenia in children but olanzapine is available on formulary if required.	
k)	**Updated - Crohn's disease: management – CG152** Dr Lim and Dr Moodie have reviewed these guidelines and advise the Trust is already compliant. Options regarding monotherapy and combined therapy are discussed with patients.	
	Clinical Guidelines for Information	
l)	**Community engagement: improving health and wellbeing and reducing health inequalities – NG44** These guidelines do not include medicines and are for information only.	
m)	**Haematological cancers: improving outcomes – NG47** These guidelines do not include medicines and are for information only.	
n)	**Routine preoperative tests for elective surgery – NG45** These guidelines do not include medicines and are for information only.	
o)	**Updated - Dementia: supporting people with dementia and their carers in health and social care – CG42** This clinical guideline has been amended to incorporate the update to NICE TA217 (see h).	
p)	**Updated - Jaundice in newborn babies under 28 days – CG98** These guidelines do not include medicines and are for information only.	
	Quality Standard for Discussion	
q)	**Medicines optimisation – QS120**	

	The Trust has a Medicines Optimisation Strategy and will review this in line with this quality standard at the MMCBG in July.	**AD/SP**
r)	**Antimicrobial stewardship – QS121** The Antibiotic Steering Group (ASG) will review this quality standard but initial thoughts are that it is a useful summary. Primary care would like to be invited to the next ASG meeting to develop better links across the interface.	**AD**
	Quality Standard for Information	
s)	**Anaphylaxis – QS119** This quality standard includes the use of adrenaline auto injectors which are already on the Trust formulary.	
	MHRA Guidance	
t) **u)**	**April 2016** **May 2016** These have been circulated to relevant Trust clinicians and are for information.	
8.	**Patient Safety Alert**	
a)	**Potassium permanganate- Risk of death or serious harm from accidental ingestion of potassium permanganate preparations 22 December 2014** This PSA was not brought to the committee in December 2014 but unfortunately the Trust have had an incident where a patient ingested potassium permanganate. The MMCBG are reviewing the incident and preparing a bulletin to inform staff and making changes to the way it is prescribed and prepared on the wards.	
9.	**Operational Issues**	
a)	**3M Tegaderm IV securement dressing for central venous and arterial catheter insertion sites** Awaiting response on audit around current practice which is being coordinated by microbiology. This will be discussed at the next ASG meeting.	**AD**
b)	**Entresto®** See 7d.	
c)	**CQUIN- Dose Banded Adult IV Systemic Anti-Cancer Therapy (SACT)** This is a NHS England CQUIN for 2016/2017 and relates to dose banding of chemotherapy. Dose banding is a system whereby drug doses which are calculated are grouped and rounded to a set of pre-defined doses. There are a number of advantages of dose banding e.g. it minimises wastage and allows optimal use of drug vials/vial sharing. It also reduces waiting times for patients as 'off the shelf' products could be used. The principles of this work are supported by the haematologists and NDAIG is asked to support the 5 principles detailed in the document. Work is ongoing to make the required changes on the electronic chemotherapy prescribing system (ChemoCare). The dosing tables are provided for information. The committee supported the principles as outlined and agreed to implement dose banding for IV adult (SACT).	
d)	**Regional Medicines Optimisation Area Prescribing Committees** The plan is still that these committees will start in Sept/Oct this year. The TOR still need to be defined and operational issues need to be addressed. Any recommendations made by the committees will need local implementation. Further updates will be provided when available.	
10.	**Feedback from CCGs and Trust Committees**	
a)	**<u>Respiratory Working Group</u>** The poster showing the inhaled therapies used for managing COPD will have Spiolto Respimat® added to it, and then circulated to staff within the Trust. The poster detailing the place in therapy of the different therapeutic classes of inhalers has been revised to include a statement on choice of device. This too	

	will be circulated. Primary care wished clinicians to be reminded of the fact that Seretide® preparations should now be used only for patients on therapy already for COPD. They also wished the group to have another meeting or information circulated on Surrey's revised place in therapy of different therapeutic classes of inhalers and the possibility of using Atimos Modulite (formoterol MDI) which is currently cheaper than other formulary LABA inhalers and Relvar® for COPD.	
b)	**<u>DOAC's</u>** **I. Update on treatment for DVT and PE with DOAC's** Work ongoing in the Trust to finalise a protocol for use. At present a group is reviewing the most appropriate assessment of renal function for the prescribing of DOAC's. In the interim there are revised prescribing guidelines for apixaban, rivaroxaban and dabigatran and a new one for edoxaban prepared by SWL Cardiac and Stroke Network. The screening checklists and notification forms for GP's have also been revised. These forms will be used once the pathway has been agreed. Confirmation needed from Surrey Downs CCG regarding duration of supply. Post meeting: This was agreed as 28 days for Surrey patients. **II. DOAC's for Pre-Cardioversion** These documents support the Trust proposal to use DOAC's for cardioversion where appropriate. Warfarin remains a treatment option and all the documents have been reviewed and agreed by the MMCBG and circulated to CCG's prior to the meeting. Final agreement from Sutton CCG will be made at their MMC meeting in July. The Trust will supply the full 10 weeks of treatment (3 before cardioversion and 4 after with an overage of supply in case of delays to appointments). Patients are asked to declare they have been compliant with treatment at pre-assessment and on the day of procedure. The GP will be sent an initiation form for information to ensure they are aware the patient is on anticoagulation. They can choose an anticoagulant of their choice after cardioversion if the CHA_2DS_2 VASc score suggests it is appropriate therapy. Documents agreed.	
c)	**<u>SWL Sutton & Merton CCG's</u>** **I. Minutes – April 2016** For information. **II. South London Algorithm for Lipid Management for the Primary and Secondary Prevention of CVD** Not discussed at this meeting. Revised version to be taken to the meeting in July.	
d)	**<u>Surrey Prescribing Clinical Network</u>** **I. Minutes – May 2016** For information. **II. Liothyronine (T3) for patients with hypothyroidism who are intolerant to levothyroxine (T4)** Trust endocrinologists support this PCN recommendation. **III. Liothyronine (T3) for patients with hypothyroidism who remain symptomatic despite optimal biochemical replacement with levothyroxine (T4)** Trust endocrinologists support this PCN recommendation. **IV. Abasaglar (Insulin Glargine- Biosimilar) for the treatment of Type I diabetes mellitus in adults, adolescents and children aged 2 years and above.** Trust endocrinologists support this PCN recommendation. **V. Abasaglar (Insulin Glargine- Biosimilar) for the treatment of Type**	

	II diabetes mellitus in adults, adolescents and children aged 2 years and above. Trust endocrinologists support this PCN recommendation. **VI. Rifaximin for preventing episodes of overt hepatic encephalopathy in people aged 18 years and older** Trust gastroenterologists support this PCN recommendation. **VII. Salofalk (mesalazine) gastro-resistant prolonged release granules for acute and maintenance treatment of mild to moderate ulcerative colitis** Trust gastroenterologists support this PCN recommendation.	
e)	**<u>Shared Care Prescribing Guidelines</u>** **I. Somatropin for Growth Failure in Children** Dr Alston has support these revised shared care guidelines. **II. Azathioprine (AZA) and 6-Mercaptopurine (6MP) for Inflammatory bowel disease (IBD) in adults (unlicensed)** Epsom gastroenterologists have supported this shared care guideline. **III. Rifaximin for the reduction in recurrence of episodes of overt hepatic encephalopathy in patients ≥ 18 years** The Trust gastroenterologists have supported this shared care guideline. **IV. Tapentadol prolonged-release (Palexia SR) for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesia** The Trust pain team have supported this shared care guideline. **V. Colesevelam for the management of bile acid malabsorption in non-cancer indications for adults** The St Helier gastroenterologists have supported this shared care guideline.	
11.	**Any Other Business** None for this meeting.	
12.	**Date of Next Meeting:** Wednesday 10th August 2016, 12.30-2.00pm, Pink Room, Ground Floor, B Block, St Helier Hospital.	