**EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST**

**NEW DRUG AND INTERFACE GROUP**

MINUTES OF THE MEETING HELD ON WEDNESDAY 8th February 2017
IN UNDERGRADUATE SEMINAR ROOM 3, FERGUSON HOUSE, ST HELIER HOSPITAL

**Present:**
Dr S Patel (Chair) **SP**
Dr P O'Mahony (Consultant Stroke Physician) **PO**
Dr L Mulleague (Consultant Anaesthetist) **LM**
Dr M Gardner (Consultant Anaesthetist) **MG**
Sharon Kitkatt (Consultant Nurse – Acute Pain Service) **SK**
Anne Davies (Chief Pharmacist) **AD**
Anne Lowson (Secretary) **AL**
Sophie Bye (Senior Pharmacist Sutton CCG) **SB**
**In attendance:**
Dr A Bansal (Consultant Immunologist) **AB**
Sumbo Adeyemo (Medicines Management Pharmacist) **SA**
Vanya Slavova Boneva (Medicines Management Pharmacist) **VSB**
Kuljit Gata-Aura (Medicines Management Technician) **KGA**
Ria John (Medicines Management Administration Coordinator) **RJ**

| No | Item | Responsible for Action |
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| **1.** | **Apologies for Absence**<br>Dr Mahmood (Consultant Gastroenterologist) **AM**<br>Dr R Shephard (Consultant Neonatologist) **RS**<br>Dr S Moodie (Consultant Gastroenterologist ) **SM**<br>Dr J Bendig (Consultant Microbiologist) **JB**<br>Dr V De Silva (Consultant Nephrologist) **VDS**<br>Dr A Pitsiaeli (GP- Surrey Downs CCG) **AP**<br>Dr R Scott (Joint Medicines Management Lead- GP Sutton CCG) **RS**<br>Liz Clark (Lead Commissioning Pharmacist, Surrey Downs CCG) **LC**<br>Sarah Taylor (Chief Pharmacist, Sutton CCG) **ST**<br>Susie Mallinder (Lead Renal Nurse) **SM**<br>Dr S Rahman (Respiratory consultant) **SR** | |
| **2.** | **Declarations of Interest**<br>No additional declarations of interest for this meeting from members or from the new drug presenters. | |
| **3.** | **Minutes of the Meeting held on the 7th December 2016**<br>Minutes were agreed. It was recognised that the meeting was not quorate; however, the committee supported the minutes of this meeting on 8th February. Dr Patel has spoken with Miss McElvanney regarding the decisions and agreed that she is given the opportunity to present any new data or clarify data presented at a future meeting, if required. | |
| **4.** | **Matters Arising** | |
| **a)** | **Ranibizumab Switching Policy**<br>No update at this meeting | **AD** |
| **b)** | **SWL – Pathway for Melatonin**<br>Proposals following the meeting with Dr Veermak are to look into possibility of | **AL/Niel Kenny/ST** |

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| | developing a transfer of care document with necessary GP education and to review costs of the liquid melatonin compared to cost of unnecessary visits / referrals to secondary care. A meeting to be arranged with pharmacy representatives from Sutton CCG, SW London and St Georges Mental Health Trust and Epsom and St Helier. | |
| **c)** | **Calcipotriol/betamethasone cutaneous (Enstilar®) foam**<br>The dermatologists discussed whether all three formulations of calcipotriol/betamethasone (ointment, gel and foam) were required on formulary and at this stage it was felt necessary due to the licensed indications and patient acceptability, which is supported by NICE. Primary care representatives to discuss with GP's patient pathways and the possibility of initiating and maintaining the treatments including Enstilar® in psoriasis. Update at next meeting. | **SB/ST/LC** |
| **d)** | **Updated – Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease**<br>No update at this meeting | **LC/ST** |
| **5.** | **New Drug Requests** | |
| **a)** | **Dymista® (azelastine with Fluticasone propionate) nasal spray**<br>Dr Bansal clarified that his request was only for symptomatic treatment of seasonal allergic rhinitis of patients where antihistamines and intranasal glucocorticoid is not considered sufficient. A request to add Dymista® to the formulary was rejected in 2013 as current trials did not compare it to oral antihistamines with intranasal corticosteroid, and it was more expensive than using separate components. A small study has been published in 2016 to show that it does improve symptoms of allergic rhinitis in patients who have failed the conventional primary care therapy. Treatment would usually start with oral or topical antihistamine and if this is ineffective a topical nasal steroid would be used. Dymista® would be used as a third line agent. Dr Bansal advised that azelastine may increase the absorption of the steroid and it would only be used for 'the season' rather than all year round. The final treatment option would be sublingual immunotherapy, and patients would prefer a nasal spray to this treatment. Patient numbers are thought to be lower than initially estimated as it would only be third line for allergic rhinitis. Dr Bansal advised that there is a management pathway for rhinitis on the Trust internet and, if agreed, this would be amended. The committee was also advised that SWL are developing a treatment pathway for this patient cohort, and the British Society for Allergy and Clinical Immunology (BSACI) are also updating their guidelines, which would be reviewed in future.<br>**Decision**<br>To add Dymista® to the formulary for use in seasonal allergic rhinitis only as a third line treatment option, after oral/topical antihistamines and intranasal steroids separately have proved ineffective. GPs to prescribe follow-up prescriptions if treatment is effective. | **VSB** |
| **b)** | **Montelukast for urticaria**<br>Dr Bansal explained that the Trust is a regional centre for management of urticaria, and would like the option to use montelukast for this condition, although it is unlicensed. First line treatment would be with antihistamines at standard doses and then if no response is seen, the dose is increased up to two, three or four times the licensed dose. Several national organisations have suggested using a leukotriene receptor antagonist (LTRA) as a third line treatment; however, the evidence is recognised to be weak. Trials do not demonstrate strong clinical evidence to refute or accept the prescribing of LTRA in patients with chronic urticaria, but they appear well tolerated with low side effect profiles. Dr Bansal would like to try treatment with montelukast in patients who have not responded to high dose antihistamines / steroids (short term). Treatment would be initially for 4 weeks and then, if successful, | |

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| | longer term until totally controlled and then gradually step down treatment. Patients would be seen approximately 3-4 monthly. For severe or resistant cases, immunosuppressants, e.g. ciclosporn may be used but strict monitoring is required, or omalizumab, which requires monthly injection.<br>**Decision**<br>To add montelukast to the Trust formulary for treatment of chronic urticaria in patients unresponsive to high dose antihistamines. This indication is unlicensed and prescribing restricted to immunology, with appropriate follow up and review. Prescribing to remain hospital only and patients to be advised of unlicensed status of this medicine. | **VSB** |
| **c)** | **Acarizax® (sublingual immunotherapy)**<br>Dr Bansal advised that this is an unlicensed medicine in the UK, but licensed in Europe for both house dust mite allergic rhinitis and allergic asthma. The request for use will be for use in patients with house dust mite sensitisation unable to achieve adequate symptom control through allergen avoidance and pharmacotherapy alone. Acarizax® is allergy immunotherapy which induces an increase in house dust mite specific Ig G4 and to induce a systematic antibody response that can compare with IgE in the binding of house dust mite allergens. Efficiency has been demonstrated in two randomised phase III controlled trials and the main treatment related adverse events are mild to moderate and subside with continued treatment. The Trust currently have Oralvac® compact liquid (unlicensed in the UK) on formulary for sublingual immunotherapy for numerous allergens including house dust mite. Acarizax® is a convenient tablet formulation given daily for 3 years, but not indicated for use in children, or adults over 65 years due to the trail data available. No comparative data between the two preparations is available, but Dr Bansal felt compliance would be better with Acarizax®. Patient numbers estimated at 15-25 per year.<br>**Decision**<br>Agreed to add Acarizax® to the formulary as sublingual immunotherapy for treatment of house dust mite allergy. Prescribing by consultant and SpR immunologists only and treatment to remain hospital only. Patients should be advised of the unlicensed status of this medicine. | **SA** |
| **d)** | **Symbicort® MDI (new formulation)**<br>Symbicort® is now available as a pressurised metered-dose inhaler (pMDI) for patients with moderate to severe COPD. Studies have shown that budesonide/formoterol pMDI is effective with side effects similar to those of the dry powder device currently on the formulary. Other pMDI combinations on the formulary which include a LABA and ICS are Fostair® (beclomethasone and formoterol). NICE advises within any category of hand held inhaler device if a patient is unable to use a particular device satisfactorily, then an alternative should be used, so it was felt useful to have this option. The request for addition to the formulary is supported by the Trust respiratory consultants and the CCGS via the Respiratory working group.<br>**Decision**<br>To add Symbicort® MDI 200/6 to the formulary for the symptomatic treatment of COPD in line with the Trust guidance for use of LABA/ICS inhaler combinations. | **SA** |
| **e)** | **Zerbaxa® (ceftolozane and tazobactam) powder for concentrate for solution for infusion**<br>This antibiotic was further discussed at the MMCBGM in January 2017, following urgent discussion at December's NDAIG. The discussion held at this meeting is detailed below.<br><br>JC (Dr John Clark consultant microbiologist) advised that he had no conflicts of | |

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| | interest to declare regarding this product. Ceftolozane and tazobactam ( Zerbaxa ®) is a new fixed combination parenteral antimicrobial agent comprising a novel 5th generation cephalosporin, ceftolozane and an established beta lactamase inhibitor tazobactam. The combination treatment is active against many gram negative pathogens including multi drug resistant Pseudomonas aeruginosa and most extended spectrum beta lactamase ( ESBL ) producing Enterobacteriaceae. There is an increase in the number of multi drug resistant gram negative organisms being seen with limited treatment options available. In some cases just a single agent colistin is the only option. There is also the national CQUIN to reduce the prescribing of carbapenems and Tazocin® which requires the Trust to reduce its usage of these agents. This new combination has increased potency against pseudomonas compared to ceftazidime. It is licensed for complicated intra-abdominal infections in combination with metronidazole, complicated urinary tract infections and acute pyelonephritis. However, the microbiologists would like to use it also where multi resistant organisms are present with limited treatment options e.g. cystic fibrosis, urology and renal patients where the limited possible options may be contraindicated or detrimental.<br>There are currently on-going trials looking at its efficacy in various respiratory conditions e.g. pneumonia. At St. George's it is restricted for resistant infections only and at The Royal Brompton Hospital it is used on consultant microbiologists advice only, last line for respiratory and transplant patients ( off label usage ). It has the advantage of being less nephrotoxic than amikacin and less nephrotoxic and neurotoxic than colistin. It is considerably more expensive than other options and the SMC have rejected its use currently. There are no head to head comparator studies against other options the Trust currently use. The committee felt that it would be essential to have a process to ensure it was only used in appropriate cases with adequate review and feedback mechanisms in place. If there was a shortage of meropenem in future and this agent was felt to be needed then it should be discussed outside of the committee due to the urgency of the request with AD/SP and the consultant microbiologists.<br><br>**Decision**<br>The committee agreed to support the decision of the MMCBGM.<br><br>To agree to add Zerbaxa® to the formulary for use on the recommendation of consultant microbiologist only following discussion at an MDT meeting. The MDT will have agreed to the validity of treatment and duration. It may be used for unlicensed indications if the above process is followed. The cost will sit with the divisions and therefore divisional directors must be informed. All cases will be audited and documented at the antibiotic steering group meetings. | **JB/DF** |
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| **6.** | **Six Month New Drug Reviews**<br>Nothing for this meeting. | |
| **7.** | **NICE/MHRA Guidance** | |
| | **Updates** | |
| | Nothing for this meeting. | |
| | **Technology Appraisals for Discussion** | |
| **a)** | **Ticagrelor for preventing atherothrombotic events after myocardial infarction – TA420**<br>The cardiologists would like to use Ticagrelor in line with this NICE TA in certain high risk cases especially post stenting with a high risk or recurrent events. To be initiated and continued on the advice of the consultant cardiologist. | **AL/KGA** |

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| **b)** | **Everolimus with exemestane for treating advanced breast cancer after endocrine therapy – TA421**<br>To be added to the Trust formulary for treating patients admitted already on treatment for advanced breast cancer after endocrine therapy. | **AL/KGA** |
| **c)** | **Crizotinib for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer – TA422**<br>To be added to the Trust formulary for use by patients admitted already on treatment for previously treated anaplastic lymphoma kinase-positive advanced non-small-cell lung cancer. | **AL/KGA** |
| **d)** | **Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens – TA423**<br>Eribulin is already on the Trust formulary but this NICE indication will be added for treating patients admitted already on treatment. | **AL/KGA** |
| **e)** | **Pertzumab for the neoadjuvant treatment of HER2-positive breast cancer – TA424**<br>To be added to the Trust formulary for treating patients admitted already on treatment. | **AL/KGA** |
| **f)** | **Dasatinib, nilotinib and high-dose imatinib for treating imatinib-resistant or intolerant chronic myeloid leukaemia – TA425**<br>These drugs are already on the Trust formulary but will be required by the haematologists for use in line with this NICE TA for treating imatinib-resistant or intolerant chronic myeloid leukaemia. | **AL/KGA** |
| **g)** | **Dasatinib, nilotinib and imatinib for untreated chronic myeloid leukaemia – TA426**<br>These drugs are on the Trust formulary but will be required by the haematologists for use in line with this NICE TA for untreated chronic myeloid leukaemia. | **AL/KGA** |
| **h)** | **Pomalidomide for multiple myeloma previously treated with lenalidomide and bortezomib – TA427**<br>Pomalidomide is already on the Trust formulary but it will also be added for use in line with this NICE TA. Funding will be via the Cancer Drugs Fund initially and then by NHS England using the Blueteq registration process. | **AL/KGA** |
| **i)** | **Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy – TA428**<br>Pembrolizumab to be added to the Trust formulary for use by patients admitted already on treatment. Funding will be via the Cancer Drugs Fund initially and then by NHS England using the Blueteq registration process. | **AL/KGA** |
| **j)** | **Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy – TA338**<br>TA428 is an updated version of TA338. | |
| **k)** | **Ibrutinib for previously treated chronic lymphocytic leukaemia and untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation – TA429**<br>Ibrutinib is on the Trust formulary but will also be added for use in line with this NICE TA for treating chronic lymphocytic leukaemia as detailed. | **AL/KGA** |
| **l)** | **Sofosbuvir-velpatasvir for treating chronic hepatitis C – TA430**<br>Patients from the Trust are currently referred to a specialist hub at either St Georges or the Royal County Surrey hospitals for treatment. Sofosbuvir is already on the formulary but velpatasvir will be added to the formulary for use by patients admitted already on treatment. | **AL/KGA** |
| **m)** | **Mepolizumab for treating severe refractory eosinophilic asthma – TA431**<br>The respiratory clinicians have advised that patients with this condition would be referred to a specialist centre for review regarding initiation and follow up, but it will be added to the formulary for use by patients admitted already on treatment. | **AL/KGA** |
| | **Technology Appraisals For Information** | |
| | Nothing for this meeting. | |

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| | **Technology Appraisals Not Recommended** | |
| | Nothing for this meeting. | |
| | **Clinical Guidelines Updated for Information** | |
| **n)** | **Hypothermia: prevention and management in adults having surgery – CG65**<br>There have been amendments to recommendations in perioperative, preoperative and intraoperative care, but they are not drug related. | |
| **o)** | **Hypertension in adults: diagnosis and management – CG127**<br>Amendments to this guideline include the MHRA drug safety alert regarding the use of ACE inhibitors in pregnancy and breastfeeding. | |
| **p)** | **Intravenous fluid therapy in adults in hospital – CG174**<br>Amendments to these guidelines include the addition of statements to report consequences of fluid mismanagement and IV fluid prescription by body weight algorithms give additional information of weight-based potassium prescriptions. | |
| | **Clinical Guidelines for Discussion** | |
| | Nothing for this meeting | |
| | **Clinical Guidelines for Information** | |
| **q)** | **End of life care for infants, children and young people with life-limiting conditions: planning and management – NG61**<br>This guideline is for information only. | |
| | **Quality Standard Updated** | |
| **r)** | **Hip fracture in adults – QS16**<br>This quality standard is for information as no drug issues identified. | |
| | **Quality Standard for Information** | |
| **s) to y)** | **Tuberculosis – QS 141**<br>For adults with HIV, an interferon-gamma release assay ( IGRA) and a concurrent Mantoux test should be used. No other drug recommendations.<br><br>**Blood transfusion – QS 138**<br>People with iron deficiency anaemia who are having surgery are offered iron supplementation before and after surgery. Adults who are having surgery are expected to have a moderate blood loss are offered tranexamic acid.<br><br>In future we will only bring Quality Standards to the committee where there are drug related issues that need to be addressed. | |
| | **Highly Specialised Technologies for Information** | |
| | Nothing for this meeting. | |
| | **Health Technology Assessment** | |
| **z)** | **Fibrin Sealants**<br>This specialised technology document relates to the use of fibrin sealants in surgical procedures to arrest haemorrhage, accumulation of post-operative fluid or blood. The document concludes that the effectiveness of fibrin sealants does not appear to vary according to surgical procedures and they appear to reduce the risk of haematoma development when used in non-emergency surgical procedures compared with standard care, but the reduction in risk of post-operative seroma development remains unproven. It also recognises that the adverse events are currently poorly reported, although no serious ones have been reported, and that the potential risk of gas embolism if spray application is not performed in line with manufacturers' recommendation needs to be recognised. Some fibrin sealants are bought through the Trust's purchasing and logistics department and there is an ongoing LPP review for rationalisation. AD to link with the group and outcome to be discussed at a future meeting if necessary. | **AD** |

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| | **MHRA Guidance** | |
| **aa)** | **December 2016**<br>The relevant sections of these alerts have been circulated to Trust clinicians. | **AL/AD/SP** |
| **8.** | **Patient Safety Alerts** | |
| **a)** | **Phenytoin**<br>A gap analysis and action plan has been devised. The Trust neurologists have revised their guidelines for status epilepticus to reflect the PSA recommendations and work is ongoing to add additional warnings to the EP prescribing system. | **AL/AD/SP** |
| **b)** | **Injecting insulin from devices**<br>The Medicines Matters Bulletin devised is awaiting final sign off. | **AD/AL** |
| **9.** | **Operational Issues** | |
| **a)** | **3M Tegaderm® IV securement dressing for central venous and arterial catheter insertion sites**<br>The infection control committee and antibiotic steering group are aware of this NICE guideline and are considering the benefits of using a clear dressing for securing central venous and arterial catheter insertion sites. Committee members felt that theatres were using Tegaderm® already, but would confirm this and contact should be made with Shila Patel (nurse specialist). | **AL** |
| **b)** | **Review of Trust Vitamin D Guidance**<br>A meeting will be held between Trust and CCG representatives after the NDAIG meeting in April. | **VSB/AL/SP** |
| **c)** | **Regional Medicines Optimisation Area Prescribing Committees**<br>The 4 regional medicines optimisation area prescribing committees are thought to be having the first meetings in April; however, the detail and process still need finalisation. There is an update meeting in London next week which is oversubscribed; however, the Trust will receive feedback from the attending CCGs. Once the TOR for the committees are available, the Trust will review the changes needed. | **AL/AD/SP** |
| **10.** | **Feedback from CCGs and Trust Committees** | |
| **a)** | **Respiratory Working Group**<br>No update for this meeting. | |
| **b)** | **DOACs**<br>**I. DVT/PE**<br>The Trust are still moving forward with the implementation of the use of DOACs for DVT and PE. IT staff are creating the forms electronically. | **AL/AD/SP** |
| **c)** | **<u>SWL Sutton & Merton CCG's</u>**<br>**I. Minutes – November 2016**<br>Update at the next meeting.<br>**II. Minutes – January 2017**<br>Update at the next meeting.<br>**III. South London Medicines Optimisation Programme (STP work stream)**<br>Update at the next meeting.<br>**IV. South West London (SWL) commissioning principles for pbR excluded drugs/devices**<br>Commissioning principles have been agreed by the Trust and shared for information with the committee. | |
| **d)** | **Surrey Prescribing Clinical Network**<br>**I. Minutes – 2016**<br>For information.<br><br>The Trust ophthalmologists support the policy statement for the use of Aflibercept for treating visual impairment caused by macular oedema after branch retinal vein occlusion. | |

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| | The Trust rheumatologists support the two policy statements.<br>Cetolizumab Pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor and Seckinumab for active ankylosing spondylitis after treatment with non-steroid anti-inflammatory drugs or TNF-alpha inhibitors.<br><br>The PCN recommends the branded prescribing of Oxycodone in line with advice from the C.Q.C. and the Trust support this.<br><br>The Trust dermatologists support the policy statement for Pimecrolimus (topical) for atopic dermatitis and Tacrolimus (topical) for atopic dermatitis. One prescription will be issued by the Trust prior to GPs being requested to continue care.<br><br>The policy statement for Lurasidone for the management of schizophrenia is noted but the Trust, but the Trust will not initiate this treatment. | |
| **11.** | **Any Other Business** | |
| **a)** | **Dates for 2017**<br>These have been circulated but the members are advised to check locations carefully as rooms have had to be rebooked due to the initiation of a new room booking system. | |
| **12.** | **Date of Next Meeting:**<br>Wednesday 5th April 2017, Boardroom, 5th Floor, Ferguson House, St Helier | |