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# DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

## Minutes of the meeting held on Tuesday 8 October 2013

# CONFIRMED MINUTES

## Summary Points

### Traffic lights

| Drug | Decision |
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| Melatonin unlicensed formulations | RED |
| Lisdexamfetamine | RED |
| Emustil (Soybean Eye Drops) | BLACK |
| Molludab (potassium hydroxide solution 5%) | RED for specialists and GPs specially trained in dermatology and dermatology champions. |
| Renavit | GREEN Specialist Recommendation |
| Apixaban | GREEN 2nd Line NOAC in accordance with AF Pathway |
| Nefopam | GREEN 3rd Line at step 2 in accordance with the chronic pain guideline |
| Tramadol | GREEN in accordance with the guideline for neuropathic and non-malignant chronic pain |
| Sildenafil chewable tablets | BROWN |
| Crizotinib | BLACK as per NICE TA 296 |

### Shared Care Guidelines

Lithium Shared Care

### Patient Group Directions

Administration of Fluenz for infants, children and adolescents (aged 2-17 years)
Administration of Seasonal Flu Vaccine

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| **Present:** | |
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| **Derbyshire County Council** | |
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| Dr J Bell | Assistant Director of Public Health (Chair) |
| Mrs S Qureshi | NICE Audit Pharmacist |
| | |
| **Southern Derbyshire CCG** | |
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| Mr S Dhadli | Specialist Commissioning Pharmacist (Secretary) |
| Mr S Hulme | Director of Medicines Management |
| Dr I Tooley | GP |
| | |
| **North Derbyshire CCG** | |
| | |
| Mrs K Needham | Head of Medicines Management North (also representing Hardwick CCG) |
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| **Hardwick CCG** | |
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| Dr T Parkin | GP (also representing North Derbyshire CCG) |
| | |
| **Erewash CCG** | |
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| Dr M Henn | GP |
| | |
| **Derby Hospitals NHS Foundation Trust** | |
| | |
| Dr F Game | Chair – Drugs and Therapeutic Committee |
| Mr C Newman | Chief Pharmacist |
| | |
| **Derbyshire Healthcare NHS Foundation Trust** | |
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| Dr S Taylor | Chair – Drugs and Therapeutic Committee |
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| **Chesterfield Royal Hospital NHS Foundation Trust** | |
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| Mr M Shepherd | Chief Pharmacist |
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| **Derbyshire Community Health Services NHS Trust** | |
| Mr M Steward | Chief Pharmacist |
| | |
| **In attendance** | |
| Ms S Berry<br>Mr A Thorpe<br>Ms J Stanney | Pharmacist, Southern Derbyshire CCG<br>Derby City Council Public Health<br>Head of Medicines Management, Southern Derbyshire CCG |

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| Item | | Action |
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| **1.** | **APOLOGIES** | |
| | Dr C Emslie, Dr D Fitzsimons, Mrs L Hunter and Dr A Mott. | |
| **2.** | **DECLARATIONS OF CONFLICT OF INTEREST** | |
| | No declarations of conflict of interest were made. | |
| **3.** | **DECLARATIONS OF ANY OTHER BUSINESS** | |
| | • Prescribing Specification.<br>• General Clinical Trials.<br>• Tramadol Consultation. | |
| **4.** | **MINUTES OF JAPC MEETING HELD ON 10 SEPTEMBER 2013** | |
| | The minutes of the meeting held on 10 September 2013 were agreed as a correct record with the following amendment:<br>List of members present – Add Dr I Tooley. | |
| **5.** | **MATTERS ARISING** | |
| **a.** | **Melatonin Feedback from Paediatricians**<br>Dr Taylor outlined the views of the DHcFT consultant paediatricians received following the September JAPC meeting who had supported the use of immediate release melatonin products for small cohorts of patients. JAPC listened to the feedback from the paediatricians which included:<br>• The view that a few children had responded well to melatonin but did not on circadin despite crushing.<br>• Some children have great difficulty swallowing and therefore needed an alternative sustained release product (or an alternative to a sustained release product).<br><br>JAPC agreed that, if indeed the numbers are small, then it could not consider it appropriate for routine prescribing in primary care, particularly when CRH have considered that Circadin MR can be used appropriately for all child patients requiring melatonin.<br><br>**Agreed:** Melatonin (excluding Circadin MR) classified as a **RED** drug. Circadin MR would continue to be classified as brown specialist initiation for children. | **SD** |
| **b.** | **Metoclopramide**<br>Mr Newman reported that a previous MHRA drug safety update had advised that the maximum dosage of metoclopramide should be 30mg and treatment should be for no longer than five days. This advice had been reviewed by the palliative care consultants and they were not in agreement with this and found metocoploramide to be a useful agent particularly in certain situations. The consultants would like the option to prescribe higher than 30mg a day in appropriate situations and for longer periods than five days. Mr Dhadli commented that Dr Game had previously indicated that metoclopramide had been used with patients with gastroparesis although this was now contraindicated and therefore put GPs in a potentially awkward position. Mr Newman stated that it had been decided to support the palliative consultants in RDH in their use of metoclopramide above the thresholds indicated in the MHRA safety update and put this on the Trust Risk Register. Mr Hulme | |

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| | suggested that the issues in the MHRA alert concerning metoclopramide could be raised with prescribers but its continued use could be recommended on specialist advice. The GPs who prescribed could record that they had taken specialist advice and this had been considered in the decision to prescribe.<br><br>**Action:** It was agreed that this advice should be highlighted in the bulletin. Mr Dhadli requested a statement from the consultants at RDH and CRH for next month. | **SD**<br><br>**FG** |
| **6.** | **NEW DRUG ASSESSMENTS/TRAFFIC LIGHT ADDITIONS** | |
| **a.** | **Lisdexamfetamine**<br>Dr Taylor stated that lisdexamfetamine mesilate was a prodrug of dexamfetamine and was a second line treatment for attention deficit/hyperactivity disorder (ADHD) in children aged six years of age and over. Mr Dhadli reported that lisdexamfetamine had been launched in 2013 for ADHD when the response to previous methylphenidate treatment was considered to be clinically inadequate. There had been three controlled trials of lisdexamfetamine of which the most useful was Coghill et al in 2013. The four week Biederman study had been conducted in the USA and showed similar results to the pivotal study. The longer maintenance study of Coghill et al in 2012 had yet to be published. It was not yet classified as a schedule 2 controlled drug and was under review by the Advisory Council on the Misuse of Drugs. The Royal Pharmaceutical Society had issued interim advice to indicate that lisdexamfetamine should be treated as though it was a schedule 2 controlled drug. The clinical evidence compared with placebo demonstrated a significant improvement in the symptoms of ADHD as measured with the ADHD-RS-IV rating scale and for secondary outcomes of clinical global impression. The NICE review was based on the Coghill et al pivotal study which was a seven week double-blind RCT in 48 centres across Europe. Mr Dhadli added that longer published data would be useful as ADHD was a long term condition. There was potential increased adherence with once daily dosing and the capsules could be dissolved in water or swallowed as a liquid which could not be done with atomoxetine which was the usual second or third line treatment.<br><br>In connection with drug misuse Mr Dhadli highlighted that the drug manufacturer had indicated that the prodrug formulation was substantially resistant to commonly available chemical or enzymatic techniques. The SMC had found that the rates of non-medical use of lisdexamfetamine were similar to extended release methylphenidate. The SPC had noted that patient preference was for the higher strength drug. The costs were significantly higher than dexamfetamine and methylphenidate but less than atomoxetine. Mr Dhadli stated that lisdexamfetamine was clinically effective against placebo and the ADHD-IV4 ratings. It was cost effective compared to atomoxetine and there would be a need to be cautious about the claim that it was non habit-forming. The theoretical benefits of increased adherence and reduced misuse potential required further discussion and long-term study.<br><br>During discussion Dr Taylor commented that lisdexamfetamine would be more effective in the first two or three weeks of treatment than atomoxetine. Mr Dhadli referred to the NICE guidance that recommended the first-line use of methylphenidate, for patients without significant co-morbidities or morbidity | |

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| | conduct disorders, followed by atomoxetine. In the event of failure with atomoxetine and non-toleration to methylphenidate the patient would go on to higher doses and then switched to dexamfetamine. Dr Taylor commented that it was proposed to retain the use of methylphenidate as first-line in the majority of cases followed by atomoxetine. The place of lisdexamfetamine would be second-line to atomoxetine in cases of failure.<br><br>**Agreed:** Lisdexamfetamine classified as a **RED** drug.<br><br>**Action:** The shared care agreement would be revised and brought back to JAPC for re-classification as amber.<br><br>**Action:** Dr Taylor would discuss the possibility of moving patients from dexamfetamine to lisdexamfetamine in view of the potential for reduction in risks related to diversion. | **SD**<br><br>**ST**<br><br>**ST** |
| **b.** | **<u>Soybean Eye Drops (Emustil)]</u>**<br>Mr Dhadli stated that Emustil was a new product which contained soybean oil for the treatment of evaporative dry eye. Evaporative dry eye being the most common form of dry eye. The cost of Emustil was £6.22p for twenty units and could be used four times a day. Evidence specifically for Emustil is limited and Mr Dhadli referred to the McCann study, the published trial for Emustil, which had compared sodium hyaluronate, hydroxypropyl methylcellulose and Emustil which showed a mixed response. It was highlighted that many of these products were medical devices and therefore only required safety data and not a clinical trial to determine their effectiveness. Evidence of preparations to treat dry eye are unconvincing low level studies. A further study had compared another product Cationorm in patients with moderate dry eye with Emustil eye drops. This had demonstrated that Cationorm was more effective than Emustil and this had highlighted the lack of comparative studies.<br><br>**Agreed:** Emustil classified as a BLACK drug. | **SD** |
| **c.** | **<u>Molludab (5% Potassium Hydroxide Solution)</u>**<br>Mr Dhadli stated that Molludab was a 5% potassium hydroxide solution used to treat molluscum contagiosum (MC) and highlighted the key points:<br>• MC was a viral skin infection most commonly seen in immuno-compromised patients and pre-school children.<br>• MC was a self-limiting condition which took between twelve to eighteen months to clear.<br>• Complications were uncommon.<br>• Treatment was not usually recommended but certain techniques could be used to treat the lesions.<br>• The annual incidence of new presentations was 261 per 100,000 and 1,265 per 100,000 in children under 15 years of age.<br>• Very few randomised controlled studies and mainly these had been carried out in a secondary care setting.<br>• A Cochrane Review in 2009 did not recommend the use of Molludab and suggested that a well designed prospective blind randomised controlled study be undertaken on common treatment options against a credible placebo. | |

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| | • The Cochrane library database had outlined a trial of the topical application of potassium hydroxide (10% and 15%) in the treatment of MC. This had suggested that daily applications of potassium hydroxide at 10% and 15% concentration could lead to reduced referrals to dermatology and paediatric departments and could be an alternative to current invasive treatments.<br>• The cost of Molludab was £13.50 for 2mls applied to the affected area twice a day and to be stopped after fourteen days.<br><br>Mr Dhadli highlighted that a 2009 Cochrane review had concluded that it was unconvinced about the evidence to offer recommendations. Studies that did exist were small, uncontrolled and mainly in a secondary care setting. Mr Dhadli also highlighted that current referrals for MC e.g. patients who are HIV positive with extensive MC lesions, eye lid or ocular lesions and adults with anogenital lesions would not be saved as this is not recommended in these circumstances.<br><br>Dr Tooley commented that MC was a self-limiting condition for which treatment should be avoided wherever possible. It was therefore difficult to see a use for this product.<br><br>**Agreed:** Molludab classified as a **RED** drug for specialists and GPs specially trained in dermatology and dermatology champions. | **SD** |
| **d.** | **<u>Renavit</u>**<br>Mr Newman stated that Renavit was a multivitamin for dialysis patients containing water soluble vitamins and marketed for the dietary management of water soluble vitamin deficiency in renal failure patients receiving haemodialysis. Renavit was an alternative product to Dialyvit which was unlicensed and imported from the USA at significant cost. The vitamin content of Renavit was very similar to Dialyvit and licensed for use in the UK and was cheaper. Mr Newman added that RDH planned to swap all haemodialysis patients to Renavit and that specialised commissioning only took account of drugs involved in dialysis and Renavit was not one of these.<br><br>During discussion Mr Dhadli stated that specialised commissioning had been contacted to check whether the dietary management of water soluble vitamin deficiency in dialysis patients was in tariff and had been informed that it was. It would therefore be necessary to decide whether this was within the envelope of costs for patients going in for haemodialysis or whether the CCGs should fund if the appropriate setting for the drug was primary care. Mr Dhadli added that the cost of Renavit was £12.50 for 100 tablets compared to £22.40 for Dialyvit and that discussion was needed as to the appropriate place for this treatment. Dr Game commented that many of these patients were dialysed at home and RDH was picking up the cost. Dr Henn stated that the use of vitamin supplementation was likely to increase in future and become part of standard treatment.<br><br>**Agreed:** Renavit classified as a **GREEN specialist recommendation** drug for dialysis patients.<br><br>Mrs Needham and Mr Hulme commented on the need to indicate to the CCGs the possibility of an unpredicted cost pressure and any supply problems from | **SD** |

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| | the wholesalers. Mr Hulme queried whether prescribing should lie where the dialysis took place. Dr Bell highlighted that it would be important to ascertain how the drug was funded and that the decision to classify Renavit as a green specialist recommendation drug should not set a precedent for any future decisions. This would be highlighted in the traffic lights. | **SD** |
| | **Action:** Mrs Needham would check with the wholesalers whether renavit was available and inform community pharmacies accordingly. Mrs Needham was concerned that, as Renevit is not a licensed medicine, there could potentially be significant out of pocket expenses. | **KN** |
| **e.** | **<u>Nefopam/Apixaban/Tramadol</u>**<br>Mr Dhadli advised that nefopam, apixaban and tramadol had been included into the Derbyshire wide formulary so now required traffic light classification. | |
| | **Agreed:** Apixaban classified as **GREEN 2nd line option** to rivaroxaban for the AF condition. Dabigatran remained as a treatment option in patients who were unable to tolerate or contra-indicated to rivaroxaban and apixaban. | **SD** |
| | **Agreed:** Nefopam classified as **GREEN 3rd line** treatment in step two for the management of chronic pain. Nefopam may be a treatment option if paracetamol, NSAID and opioids could not be tolerated or patients were unresponsive to non-opioid analgesics. | **SD** |
| | **Agreed:** Tramadol classified as a **GREEN** drug for use in the neuropathic and non-malignant chronic pain guideline. | **SD** |
| **7.** | **PATIENT GROUP DIRECTIONS (PGDs)** | |
| **a.** | Mr Dhadli referred to comments received from Ms Caroline Jordan, Screening and Immunisation Manger, NHS England Area Team Derbyshire and Nottinghamshire, who had indicated that the Area Team proposed to share the development of PGDs with appropriate sign off by the relevant APC. Once signed off the organisational authorisation for use in primary care would be undertaken by Dr Doug Black, Area Team Medical Director. During discussion about the role of JAPC in response to the PGDs produced by the Area Team Mr Hulme highlighted that some PGDs had been sent out without any local consultation and the clinical content should be agreed by the relevant APC for the area in which the hosting CCG was located. However the sign-off was the responsibility of the Area Teams but these would need to be agreed by JAPC before being put on the website which would indicate endorsement by the APC. Dr Parkin commented that it was important that GPs knew where to look for PGDs and to be assured that they had been approved. Dr Bell suggested that part of the website could indicate that some of the PGDs had been issued nationally and had not received local approval. It would be important to obtain clarity on the PGD process and that they continued to be presented to JAPC.<br><br>Mr Dhadli referred JAPC to the PGDs for Fluenz and General Flu Vaccinations. Mrs Needham commented that the objectives section of the Fluenz PGD should be amended to read 'The ultimate objective of the extended infuenza vaccination programme is to provide a single dose of Fluenz to infants and children from two years to seventeen years of age who are not in a risk category | |

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| | and in order to prevent symptoms and spread of infection with influenza virus.' Mr Dhadli would highlight this amendment to the Area Team.<br><br>**Agreed:** JAPC ratified the PGD for the administration of Fluenz with the agreed amendment.<br><br>**Agreed:** JAPC ratified the PGD for the administration of seasonal flu vaccine. | **SD**<br><br>**SD** |
| **8.** | **SHARED CARE GUIDELINE** | |
| **a.** | **Lithium Shared Care**<br>Dr Taylor highlighted the amendments which had been made to the sections which referred to GP/Consultant responsibilities, communications, monitoring requirements and clinically relevant drug interactions.<br><br>**Agreed:** JAPC ratified the lithium shared care guideline. | **SD** |
| **9.** | **MONTHLY HORIZON SCAN** | |
| | Mr Dhadli advised JAPC of the following new drug launches and new drug formulations:<br>Sodium hydrogen carbonate 500mg/sodium hydrogen phosphate 680mg – To be left as unclassified awaiting request for its use.<br><br>Sildenafil chewable tablets – JAPC classified as a **BROWN** drug.<br><br>Oxybutynin elixir – To be left as unclassified and not to be added to the database.<br><br>Bimatoprost/timolol preservative-free eye drops – To be left unclassified and not to be added to the database.<br><br>Anugesic HC Suppositories – Drug has been discontinued. | **SD**<br><br>**SD**<br><br>**SD** |
| **10.** | **MISCELLANEOUS** | |
| **a.** | **Lixisenatide**<br>Mr Dhadli advised that NICE had published an evidence summary on lixisenatide for type 2 diabetes in January 2013 and JAPC had accepted its use as the preferred GLP-1 mimetic at its meeting in July 2013. However, NICE had recently issued an update which replaced the earlier evidence summary and Mr Dhadli highlighted the key points:<br>• Lixisenatide in combination with oral therapies has been investigated in three key randomised controlled trials GetGoal-P, GetGoal-M and GetGoal-X.<br>• GetGoal-P and GetGoal-M found that lixisenatide was more effective than placebo with regard to their primary outcome of reduction in HbA1c from baseline. However, the 0.8–0.9 percentage point meant reductions from baseline in the lixisenatide groups were slightly less than the 1.0 percentage point (11 mmol/mol) reduction specified in NICE guidance as a criterion for continuing treatment with exenatide or liraglutide in triple or dual therapy beyond 6 months and the mean difference from placebo was about half of that.<br>• GetGoal-M and GetGoal-P both found a statistically significant reduction | |

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| | in fasting plasma glucose with lixisenatide compared with placebo and GetGoal-M found a statistically significant reduction in 2-hour post-prandial plasma glucose. There was no statistically significant effect from lixisenatide on body weight compared with placebo in either study. The European Medicines Agency (EMA) concluded that the effect of lixisenatide on body weight was of clear clinical relevance and advantageous compared with the increase in weight with some other therapeutic options.<br>• GetGoal-X concluded that lixisenatide was non-inferior to exenatide with regard to the primary outcome of reduction in HbA1c from baseline. However, the EMA concluded that non-inferiority to exenatide had not been shown robustly. There was no statistically significant difference in fasting plasma glucose between lixisenatide and exenatide. Exenatide produced a statistically significantly greater mean reduction in bodyweight. Statistically significantly fewer people receiving lixisenatide reported nausea or symptomatic hypoglycaemia compared with those receiving exenatide.<br><br>Mr Dhadli was concerned around the evidence of weight reduction to meet NICE criteria and its efficacy compared to exenatide and queried the choice of lixisenatide as the preferred GLP1 across Derbyshire with this NICE review.<br><br>During discussion Dr Game referred to the current pathway which had lixisenatide and liraglutide and the huge number of patient drop-outs due to intolerance. It was anticipated that fewer patients would move from lixisenatide to liraglutide as it was better tolerated and had a once-daily administration. Mr Hulme queried whether JAPC had made the decision in July 2013 based on the right evidence and was assured that this was the case. It would be highlighted that the original decision made by JAPC would be reflected in the diabetes guidelines to be reviewed by JAPC. | **FG** |
| | **Agreed:** JAPC agreed that the earlier decision to replace exenatide with lixisenatide for new starters should continue and be reviewed in twelve months time in association with the new data. | **SD** |
| **b.** | **<u>Insulin Degludec and Efficacy of Three Times Weekly Dosing</u>**<br>Mr Dhadli reported that JAPC had recommended the use of insulin degludec in defined cohorts of patients only at its meeting in September 2013. The cohorts were:<br>• Patients who had significant problems with documented nocturnal hypoglycaemia that would otherwise have been started on insulin pump therapy which was expensive due to the costs of pumps and consumables.<br>• Patients who currently required very high doses of insulin or were considered for the concentrated Humulin R U-500 which was only available in vials and posed significant governance issues in terms of prescribing and dispensing.<br><br>Mr Dhadli stated that there had been two 26 week, randomised, open label studies which had looked at the efficacy and safety of insulin degludec three times a week versus insulin glargine once a day in insulin-naive patients with | |

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| | type 2 diabetes. The interpretation of the trials had revealed the inferior glycaemic control and increased risk of hypoglycaemia with insulin degludec compared with insulin glargine and did not support a three times weekly dosing regimen. Dr Game stated that the original submission for the use of degludec three times weekly had not been approved by the RDH Drugs and Therapeutic Committee.<br><br>**Agreed:** JAPC did not support the use of insulin degludec three times a week. | |
| **c.** | **<u>Gender Reassignment Update</u>**<br>Mr Dhadli reported that the NHS England Area Team had been requested to produce a protocol and service outline for gender dysphoria in order to address the inequity in services in England. An interim policy had been developed and approved by the Clinical Priorities Advisory Group and this was currently awaiting ratification by the NHS England Board.<br><br>It is likely that the policy would be very similar to the Scottish protocol and the prescribing of hormone therapy treatments off-licence and the monitoring required. In order to aid GP prescribing that may already be taking place Mr Dhadli would put a link in the bulletin to signpost GPs to the guidance. | **SD** |
| **d.** | **<u>Excess Treatment Costs</u>**<br>Mr Dhadli referred to the advice to be offered to the CCGs on the drugs included in trials in order to highlight risks to prescribing budgets and deviation from locally agreed guidelines and pathways. Mr Dhadli outlined the five questions to be addressed by JAPC on two trials together with the responses.<br>Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease (BARACK D) Trial:<br>• Is the drug on the preferred formulary? Yes but was indicated for Heart Failure (HF).<br>• What is the financial risk to the CCGs during and on completion of the trial? Minimal financial risk to CCGs.<br>• Will prescribing of this drug influence GP prescribing outside the clinical trial? No as the numbers involved were too small.<br>• Are there any clinical concerns that will undermine local prescribing advice? Possibly as current use was currently only within HF guidance.<br>• Does the trial conflict with the CCGs strategic position/direction? No as the aim is to reduce admissions and prevent death.<br><br>Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease (ALL-HEART):<br>• Is the drug on the preferred formulary? Yes currently classified as a green drug.<br>• What is the financial risk to the CCGs during and on completion of the trial? The financial cost at the upper end of patient recruitment would be £38k across Derbyshire.<br>• Will prescribing of this drug influence GP prescribing outside the clinical trial? This depended on the outcome of the study.<br>• Are there any clinical concerns that will undermine local prescribing advice? Unlikely.<br>• Does the trial conflict with the CCGs strategic position/direction? No. | |

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| | The CCG representatives of JAPC would convey these responses to their organisations. | **CCG Reps** |
| **11.** | **JAPC BULLETIN** | |
| | Dr Bell highlighted that the bulletin referred to the forthcoming review by the CCGs of the new Varicose Vein Guidelines (CG 168) but in the interim the current Procedure of Limited Clinical Value (PLCV) guidelines still applied.<br><br>In connection with the Drug Safety Update with nitrofurantoin Mr Newman advised that that the RDH Antimicrobial Group did not want to stay with the <60ml/min creatinine clearance stated in the bulletin and preferred a creatinine clearance of <40ml/min. Mr Shepherd commented that this was the position at CRH as well. Dr Tooley expressed concern that GPs would find using creatinine clearance over eGFR impracticable. Mr Newman would request the Antimicrobial Group to develop some wording which could be included in the next JAPC bulletin.<br><br>The amended JAPC bulletin was ratified by JAPC. | **CN**<br><br>**SD** |
| **12.** | **MHRA DRUG SAFETY UPDATES** | |
| | The MHRA Drug Safety Update for September 2013 was noted. | |
| **13.** | **NICE SUMMARY** | |
| | Mrs Qureshi informed JAPC of the comments for the CCGs which had been made for the following NICE guidance issued in September:<br><br>TA 296 Crizotinib for previously treated non small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene.<br>Crizotinib classified as a **BLACK** drug.<br><br>CG 171 Urinary Incontinence: The management of urinary incontinence in women.<br>The guideline updated and replaced the previous NICE guidance on urinary incontinence in women published in October 2006. In terms of prescribing NICE recommended as first line oxybutynin immediate release, tolterodine immediate release or darifenacin once daily preparation. Darifenacin had been included in the economic analysis as it was the only one which was once-daily and had the highest probability of being cost effective. It was highlighted that oxybutinin immediate release should not be given to frail elderly people and this should be included in the guidance. Although mirabegron had not been one of the drugs assessed in the guideline it had been separately approved for use in the treatment of overactive bladder where other treatments were contraindicated. NICE recommended that two treatments be tried and then women could be referred to secondary care where they could go on to have treatment with botulinum toxin A or sacral nerve stimulation. Mr Dhadli queried whether duloxetine, which had previously received a traffic light classification, should be included in the pathway although it was not recommended as either first-line or second-line for severe stress urinary incontinence but only for women who did not wish to have surgery and preferred a pharmacological treatment. It was agreed that the existing guideline should be reviewed against the NICE guidance and the views of the consultant urologists obtained. | **SD** |

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| **15.** | **TRAFFIC LIGHTS – ANY CHANGES?** | |
| | **Classifications**<br>Melatonin – RED<br>Lisdexamfetamine – RED (awaiting shared care guideline)<br>Emustil (Soybean Eye Drops) – BLACK<br>Molludab – RED for specialists and GPs specially trained in dermatology and dermatology champions.<br>Renavit – GREEN specialist recommendation<br>Apixaban – GREEN 2nd line in accordance with the AF pathway<br>Nefopam – GREEN 3rd line in accordance with the chronic pain guideline<br>Tramadol – GREEN in accordance with the guideline for neuropathic and non-malignant chronic pain.<br>Sildenafil chewable tablets – BROWN<br>Crizotinib - BLACK | |
| **16.** | **JAPC ACTION SUMMARY** | |
| | The action summary was noted by JAPC and amendments made:<br><br>Shared Care Disulfiram – Still waiting for clarity on medically managed and monitoring requirements in first six months.<br><br>Transgender Prescribing – Already discussed by JAPC.<br><br>Melatonin – To be removed from the list.<br><br>Actinic Keratosis – Dr Bleiker from RDH was liaising with Dr Graham Clover from CRH in order to develop some guidance.<br><br>Rivaroxaban – Mrs Needham would work with Ms Ann Hayes from Derbyshire County Council Public Health Directorate to develop a DVT pathway.<br><br>Rifaxamin for HE – NICE guidance was awaited.<br><br>Diabetes Guidelines – The diabetes guidance was to be discussed by the Guidelines Group. | **SD**<br><br>**SD**<br><br>**SD**<br><br>**SD**<br><br>**KN**<br><br>**SD**<br><br>**SD** |
| **17.** | **GUIDELINE GROUP** | |
| | The Guideline Group action tracker was ratified by the JAPC after the inclusion of Dr I Tooley in the attendance list. | **SD** |
| **18.** | **MINUTES OF OTHER PRESCRIBING GROUPS** | |
| | • Sheffield Area Prescribing Group – June 2013<br>• Chesterfield Drugs and Therapeutics Committee – July 2013<br>• Burton Drugs and Therapeutics Committee – September 2013<br>• DHcFT Drugs and Therapeutic Committee – July 2013<br>• Stockport CCG Area Medicines Panel – August 2013 | |
| **19.** | **ANY OTHER BUSINESS** | |
| **a.** | **Prescribing Specification**<br>Mr Dhadli reported that the prescribing specification formed part of the contract with the providers. The prescribing specification now needed to be amended | |

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| | and comments conveyed to Mr Dhadli. | |
| **b.** | **General Clinical Trials**<br>Mrs Needham referred to a query received from a GP practice which had been sent a pharmaceutical funded trial directly concerning 1.8mg liraglutide in patients with type 2 diabetes, on metformin alone and its impact on reducing BMI. It had been queried whether JAPC should encourage active engagement with clinical trials and highlighted that the exit strategy and the patient information leaflet should make absolutely clear that there was no ongoing prescribing responsibility. Mr Dhadli had contacted the Primary Care Research Network (PCRN) for the Trent Region and it had been confirmed that a database of all the trials was maintained but the clinical content was not looked at. Dr Game highlighted the necessity of ensuring that no costs were passed on to CCGs, particularly at the end of the trials, and the role of JAPC in informing the decision making bodies who funded the trials. Dr Bell commented that the PCRN had a performance measure which recorded the number of practices and patients recruited on to trials. It was agreed that these trials should be brought to the JAPC meetings for discussion for a trial period of two months and reviewed after that. | **SD** |
| **c.** | **Tramadol Consultation**<br>Mr Newman reminded JAPC that the Home Office consultation on the proposal to make Tramadol a Class C drug closed at the end of the week and any comments should be conveyed before this time. | **All members** |
| **d.** | **Syringes for Syringe Drivers**<br>Mr Steward reported that a query had been raised by a DCHS hospital as to whether the two systems currently in use in the north and the south of the county for the preparation of syringes for syringe drivers should be standardised. The current situation was that in the north GPs and the district nurses went into a patient's home in order to make up the syringe for syringe drivers but in the south the CCGs commissioned a pharmacy department to prepare these aseptically and then deliver these within four hours. Mr Steward stated that there had consequently been a few errors by the nurses or by DHU who also worked across the county which were attributable to the use of the two different systems. Mr Steward queried whether the CCGs were happy to continue with the two systems. Mr Hulme and Mrs Needham highlighted the need to share knowledge about any incidents particularly those which involved DHU but it was agreed that any change to the current systems was not feasible. | |
| **20.** | **DATE OF NEXT MEETING** | |
| | Tuesday, 12 November 2013 in the Post Mill Centre, South Normanton. | |